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DEPARTMENT OF HOMELAND SECURITY

6 CFR Part 27

[Docket No. CISA–2021–0007]

Chemical Facility Anti-Terrorism Standards: Technical Amendments

AGENCY: Cybersecurity and Infrastructure Security Agency, DHS.

ACTION: Final rule.

SUMMARY: This final rule makes non-substantive technical, organizational, and conforming amendments to the Chemical Facility Anti-Terrorism Standards.

DATES: This final rule is effective August 4, 2021.

FOR FURTHER INFORMATION CONTACT: Lona Saccomando, (202)–579–0590, *CISARegulations@cisa.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Regulatory History

We did not publish a notice of proposed rulemaking for this rule. Under Title 5 of the United States Code (U.S.C.), Section 553(b)(A), the Cybersecurity and Infrastructure Security Agency (CISA) finds that this final rule is exempt from notice and public comment rulemaking requirements because notice and comment procedures are unnecessary for this final rule under 5 U.S.C. 553(b)(B), as this rule consists of only technical and editorial corrections and these changes will have no substantive effect on the public. Under 5 U.S.C. 553(d)(3), CISA finds that, for the same reasons, good cause exists for making this final rule effective upon publication in the **Federal Register**.

II. Basis and Purpose

CISA is issuing technical, organizational, and conforming amendments to existing regulations in part 27 of title 6 of the Code of Federal Regulations (CFR), relating to the Chemical Facility Anti-Terrorism Standards (CFATS). These technical amendments provide the public with more accurate and current regulatory information, but do not change the effect on the public of these regulations.

This final rule makes technical and editorial corrections to the CFATS regulations. These changes are necessary to correct errors, change addresses, update titles, and make other non-substantive amendments that improve the clarity of the CFR. This rule does not create or change any substantive requirements.

This final rule is issued under the authority of 5 U.S.C. 552(a), 5 U.S.C. 553, and 6 U.S.C. 627.

III. Discussion of the Rule

Until 2018, the CFATS program was administered by the Office of Infrastructure Protection of the National Protection and Programs Directorate (NPPD) of the Department of Homeland Security (DHS). In 2018, Congress passed the Cybersecurity and Infrastructure Security Agency Act of 2018, redesignating NPPD as CISA, and establishing CISA as a component of DHS. To account for the organizational changes, throughout the regulatory text of 6 CFR 27, in this rule CISA is replacing the titles for various organizations within the Department, previously responsible for operating the CFATS program, with the appropriate titles of CISA personnel and organizations. We have replaced references to ''National Protection and Programs'' and ''Office of Infrastructure Protection'' with ''Cybersecurity and Infrastructure Security Agency.'' We have replaced references to the ''Chemical Security Division'' with ''Chemical Security.'' We have also replaced references to the Under Secretary, Assistant Secretary, and Director of the Chemical Security Division with references to the Director, Executive Assistant Director, and Associate Director for Chemical Security, respectively. CISA has also replaced references to the Office of General Counsel of DHS with references to the Office of the Chief Counsel of CISA, where appropriate. These changes have been made throughout 6 CFR part 27. We have also removed the definition of ''Deputy Secretary'' because it is not referenced in the regulatory text.

We have replaced references to ''section 550,'' which refers to the original numbering from the Homeland Security Appropriations Act 2007, with language referring to ''this part'' or references to the U.S. Code citation—6 U.S.C. 621 *et seq.*—to reflect changes in statutory numbering. We have removed gendered references to officials (*e.g.,* ''his designee,'' or ''his staff'') and used gender-neutral terms where appropriate. In several sections, CISA has made grammatical or stylistic corrections to fix minor errors in the regulation such as consistent use of the Oxford comma and consistently hyphenating the term ''high-risk'' when it is used as an adjective. We discuss select additional specific changes below, and note that this is not an exhaustive list of changes. For an exhaustive list of changes, please see the amendatory instructions at the end of this document.

In section 27.105, CISA updates the definition of *A Placarded Amount* to spell out the acronym STQ. In the definition of Alternative Security Program we capitalize the word ''State.'' In the definition of *Chemical Security Assessment Tool or CSAT* we remove the list of examples from the definition. CISA is adding a new definition for the term *Office of the Chief Counsel* to clearly indicate the term refers to the Office of the Chief Counsel within CISA. In the definition of *CUM 100g,* CISA is clarifying that the term is used only in the context of chemical weapons themselves, which are a subset of the ''Theft—CW/CWP'' category. In the definition of *Secretary,* CISA is replacing the citation to section 550 with a citation to 6 U.S.C. 621 *et seq.,* to make the citation easier to find. Finally, we are correcting a citation in the definition of *Terrorist attack* or *terrorist incident* by replacing a citation to the definition of *terrorism* or *terrorist activity,* previously noted as 6 U.S.C. 101(15), with a citation to 6 U.S.C. 101(16).

In section 27.110(b), CISA is rewording the reference to excluded facilities by replacing the existing language with a clear reference to statutory exclusions in 6 U.S.C. 621(4) and breaking down the long paragraph on excluded facilities into four subsections to make clear that the regulatory language does not change the scope of the statutory exemption.

In section 27.210, CISA is adjusting the language in paragraph (b)(1) to make clear that the requirement to complete

and submit a new Top-Screen is calculated from the date of the approval of the facility's latest Security Plan. Additionally, CISA is splitting the paragraph into two sub-paragraphs to improve readability, and removing an extra space in paragraph (b)(3).

In section 27.400, CISA is correcting a citation to the Federal Records Act in paragraph (k), replacing an inaccurate U.S. Code reference to the proper citation to that Act.

Numerous other changes to style, language, and punctuation are being made in this technical amendment. In the text above, we discussed the particulars of some of the more significant changes. Examination of the amendments to the regulatory text below will the detail numerous additional edits to grammar, punctuation, abbreviation, and numbering that have been made in this document.

List of Subjects in 6 CFR Part 27

Reporting and recordkeeping requirements, Security measures.

For the reasons set forth in the preamble, the Department of Homeland Security amends 6 CFR part 27 as follows:

PART 27—CHEMICAL FACILITY ANTI-TERRORISM STANDARDS

■ 1. The authority citation for part 27 is revised to read as follows:

Authority: 6 U.S.C. 624; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 114–74, 129 Stat. 599; Pub. L. 113–254, 128 Stat. 2898, as amended by Pub. L. 116–150, 134 Stat. 679.

§ 27.100 [Amended]

■ 2. Amend § 27.100 by removing the ''§ '' symbol after the term ''6 U.S.C.''.

■ 3. Amend § 27.105 as follows:

■ a. In the definition of ''*A Placarded Amount*'' remove the term ''STQ'' and add, in its place, the term ''screening threshold quantity (STQ)'';

■ b. In the definition of ''*Alternative Security Program or ASP*'':

■ i. Remove the word ''state'' and add, in its place, the word ''State'';

■ ii. Add a comma after the term ''Federal government program''; and

■ iii. Remove the term ''Assistant Secretary'' and add in its place the term ''Executive Assistant Director'';

■ c. Add, in alphabetical order the definition of ''*Associate Director for Chemical Security*'';

■ d. Remove the definition of ''*Assistant Secretary*'';

■ e. In the definition of ''*Chemical Facility or facility*'', remove the term ''Assistant Secretary'' and add in its place the term ''Executive Assistant Director'';

■ f. In the definition of ''*Chemical Security Assessment Tool or CSAT*'', remove the phrase ''four applications, including User Registration, Top-Screen, Security Vulnerability Assessment, and Site Security Plan,'' and add in its place the word ''applications'';

■ g. In the definition of ''*Chemical-terrorism Vulnerability Information*'', remove the phrase ''or CVI'' and add, in its place, the term ''(CVI)'';

■ h. In the definition of ''*Coordinating Official*'':

■ i. Remove the word ''his''; and

■ ii. Remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director'';

■ i. In the definition of ''*Covered Facility or Covered Chemical Facility*'', remove the term ''Assistant Secretary'' wherever it appears and add in its place, the term ''Executive Assistant Director'';

■ j. Revise the definition of *CUM 100g;*

■ k. Remove the definition of ''*Deputy Secretary*'';

■ l. Add, in alphabetical order the definition of ''*Director*'';

■ m. Remove the definition of ''*Director of the Chemical Security Division or Director*'';

■ n. Add, in alphabetical order the definition of ''*Executive Assistant Director*'';

■ o. Remove the definition of ''*General Counsel*'';

■ p. Add, in alphabetical order the definition of ''*Office of the Chief Counsel*'';

■ q. In the definition of ''*Present high levels of security risk and high risk*'', add a comma after the term ''national security'';

■ r. In the definition of ''*Risk profiles*'', remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director'';

■ s. In the definition of ''*Secretary or Secretary of Homeland Security*'':

■ i. Add a comma after the word ''officer''; and

■ ii. Remove the term ''section 550'' and add, in its place, the term ''6 U.S.C. 621 *et seq.*'';

■ t. In the definition of ''*Security Issue*'':

■ i. Remove the comma from the end of paragraph (2) and add in its place a semicolon;

■ ii. Remove the comma from the end of paragraph (3) and add in its place ''; and''

■ u. In the definition of ''*Terrorist attack or terrorist incident*'':

■ i. Remove the term ''6 U.S.C. 101(15)'' and add, in its place, the term ''6 U.S.C. 101(16)''; and

■ ii. Add a comma after the word ''misappropriation'';

■ v. In the definition ''*Tier*'', remove the term ''and which'' and add, in its place, the word ''that'';

■ w. In the definition ''*Top-Screen*'', remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director''; and

■ x. Remove the definition of ''*Under Secretary*'';

The revisions and additions read as follows:

§ 27.105 Definitions.

* * * * *

Associate Director for Chemical Security shall mean the Associate Director for Chemical Security, Infrastructure Security Division, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security, or any successors to that position within the Department, or designee.

* * * * *

CUM 100g shall refer to the cumulative STQ of 100 grams for designated Chemical Weapons (CW), located in appendix A to part 27 as the entry for the STQ and Minimum Concentration of certain Theft-CW/CWP chemicals.

* * * * *

Director shall mean the Director of the Cybersecurity and Infrastructure Security Agency, Department of Homeland Security, or any successors to that position within the Department, or designee.

* * * * *

Executive Assistant Director shall mean the Executive Assistant Director for the Infrastructure Security Division, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security, any successors to that position within the Department, or designee.

* * * * *

Office of the Chief Counsel shall mean the Office of the Chief Counsel of the Cybersecurity and Infrastructure Security Agency, Department of Homeland Security, or any successors within the Department.

* * * * *

■ 4. Revise § 27.110 to read as follows:

§ 27.110 Applicability.

(a) This part applies to chemical facilities and to covered facilities as set out herein; and

(b) This part does not apply to a facility that is excluded as set forth in 6 U.S.C. 621(4):

(1) A facility regulated under the Maritime Transportation Security Act of 2002 (Pub. L. 107–295; 116 Stat. 2064);

(2) A public water system, as that term is defined in 42 U.S.C. 300f;

(3) A Treatment Works, as that term is defined in 33 U.S.C. 1292;

(4) A facility owned or operated by the Department of Defense or the Department of Energy; or

(5) A facility subject to regulation by the Nuclear Regulatory Commission, or by a State that has entered into an agreement with the Nuclear Regulatory Commission under 42 U.S.C. 2021(b) to protect against unauthorized access of any material, activity, or structure licensed by the Nuclear Regulatory Commission.

§ 27.115 [Amended]

■ 5. Amend § 27.115 as follows:
■ a. Remove the term ''Assistant Secretary'' wherever it appears and add, in its place, the term ''Executive Assistant Director''; and
■ b. Remove the term ''the section 550 program'' and add, in its place, the term ''this part''.

■ 6. Amend § 27.120 as follows:
■ a. Revise the section heading;
■ b. In paragraph (a) remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director''; and
■ c. In paragraph (b) remove the term ''and his staff''.

The revision reads as follows:

§ 27.120 Designation of a Coordinating Official; consultations and technical assistance.

* * * * *

§ 27.200 [Amended]

■ 7. Amend § 27.200:
■ a. In paragraph (a) add a comma after the second use of the word ''safety'';
■ b. In paragraph (b)(1) remove the term ''Assistant Secretary'' wherever it appears and add, in its place, the term ''Executive Assistant Director'';
■ c. In paragraph (c) amend the paragraph heading by removing the words ''*High Risk*'' and adding in their place the words ''*High-Risk*'';
■ d. In paragraph (c)(1):
■ i. In the first sentence, remove the word, ''timeframe'' and add, in its place, the words ''time frame'';
■ ii. Remove the term ''Assistant Secretary'' wherever it appears, and add, in its place, the term ''Executive Assistant Director''; and
■ iii. Add a comma after the citation ''§ 27.250''.

§ 27.203 [Amended]

■ 8. Amend § 27.203 as follows:
■ a. In paragraph (a)(7):
■ i. Remove the term ''et. seq.'' and add in its place the term ''*et seq.*''; and
■ ii. Add the word ''or'' after the semicolon at the end of the paragraph;
■ b. In paragraph (a)(8) remove the term ''in naturally occurring'' and add in its place the term ''In naturally occurring'';
■ c. In paragraph (b)(1)(v):
■ i. Add a comma after the word ''kerosene'';
■ ii. Remove the term ''27.204(a)(2))'' and add in its place ''§ 27.204(a)(2)),'';
■ d. In paragraph (b)(2):
■ i. Remove the term ''(c)(2)(i)'' and add in its place the term ''(b)(2)(i)''; and
■ ii. Add a comma after the word ''processes''; and
■ e. In paragraph (c) remove the term ''theft/diversion-Chemical Weapons (CW)'' and add, in its place, the term ''theft/diversion-CW''.

■ 9. Amend § 27.204 as follows:
■ a. In paragraph (a)(2):
■ i. Remove terms, ''National Fire Protection Association (NFPA)'' and ''National Fire Protection Association'' wherever they appear and add, in their place, the term ''NFPA''
■ ii. Revise the sixth sentence;
■ b. In paragraph (b)(1):
■ i. Remove the phrase ''Theft/Diversion-Chemical Weapons (CW) and Chemical Weapons Precursors (CWP Chemicals:'' and add a paragraph (b)(1) heading; and
■ ii. Remove the term ''theft/diversion-CWC/CWP'' and add, in its place, the term ''theft/diversion-CW/CWP'';
■ c. In paragraph (b)(2) remove the phrase ''Theft/Diversion-Weapon of Mass Effect (WME) Chemicals:'' and add a paragraph (b)(2) heading;
■ d. Revise the paragraph (b)(3) heading; and
■ e. In paragraph (c) remove the phrase ''For each sabotage/contamination chemical of interest'' and add, in its place, the phrase ''For each sabotage and contamination chemical of interest''.

The revisions read as follows:

§ 27.204 Minimum concentration by security issue.

(a) * * *

(2) * * * You may inspect a copy of the incorporated standard at the Department of Homeland Security, 1621 Kent Street, 9th Floor, Rosslyn, VA (please call 703–235–0709 to make an appointment), or at the National Archives and Records Administration (NARA). * * *

* * * * *

(b) * * *

(1) *Theft/Diversion-Chemical Weapons (CW) and Chemical Weapons Precursors (CWP) chemicals.* * * *

(2) *Theft/Diversion-Weapon of Mass Effect (WME) chemicals.* * * *

(3) *Theft/Diversion-Explosives/Improvised Explosive Device Precursor (EXP/IEDP) chemicals.* * * *

* * * * *

§ 27.205 [Amended]

■ 10. Amend § 27.205 as follows:
■ a. In paragraph (a):
■ i. Remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director''; and
■ ii. Add a comma after the term ''national security''; and
■ b. In paragraph (b) remove the term ''Assistant Secretary'' wherever it appears and add, in its place, the term ''Executive Assistant Director''.

■ 11. Amend § 27.210 as follows:
■ a. In paragraph (a) remove the word ''timeframes'' and add in its place the term ''time frames'';
■ b. Revise paragraph (b)(1);
■ c. In paragraph (b)(3) remove the extra space after the word ''section''; and
■ d. In paragraph (c) remove the term ''Assistant Secretary'' wherever it appears and add, in its place, the term ''Executive Assistant Director''.

The revision reads as follows:

§ 27.210 Submissions schedule.

* * * * *

(b) * * *

(1) *Top-Screen.* Unless otherwise notified:

(i) Tier 1 and Tier 2 covered facilities must complete and submit a new Top-Screen no less than two years, and no more than two years and 60 calendar days, from the date of the Department's approval of the facility's most recent Site Security Plan.

(ii) Tier 3 and Tier 4 covered facilities must routinely complete and submit a Top-Screen no less than three years, and no more than three years and 60 calendar days, from the date of the Department's approval of the facility's most recent Site Security Plan.

* * * * *

§ 27.215 [Amended]

■ 12. Amend § 27.215 as follows:
■ a. In paragraph (a) introductory text:
■ i. Remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director''; and
■ ii. Remove the term ''high-risk'' and add, in its place, ''high risk'';
■ b. In paragraph (a)(3) remove the term ''Risk-Based Performance Standards'' and add, in its place, the term ''risk-based performance standards'';
■ c. In paragraph (b) remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director''; and
■ d. In paragraph (d)(2):
■ i. Add a comma after the word ''revise''; and
■ ii. Remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director''.

§ 27.220 [Amended]

■ 13. In § 27.220 remove the term ''Assistant Secretary'' wherever it appears and add, in its place, the term ''Executive Assistant Director''.

§ 27.225 [Amended]

■ 14. Amend § 27.225 as follows:
■ a. Remove the term ''Assistant Secretary'' wherever it appears and add, in its place, the term ''Executive Assistant Director''; and
■ b. In paragraph (d)(1) add a comma after the word ''revises''.

§ 27.230 [Amended]

■ 15. In § 27.230 remove the term ''Assistant Secretary'' wherever it appears, and add, in its place, the term ''Executive Assistant Director''.

§ 27.235 [Amended]

■ 16. In § 27.235 amend paragraph (a) introductory text by:
■ a. Removing the first use of the term, ''Alternate Security Program'' and adding, in its place, the term, ''Alternative Security Program'';
■ b. Removing the term ''Assistant Secretary'' and adding, in its place, the term ''Executive Assistant Director''; and
■ c. Removing the second and third uses of the term ''Alternate Security Program'' and adding, in their places, the term, ''ASP''.

§ 27.240 [Amended]

■ 17. Amend § 27.240 as follows:
■ a. In paragraph (a) remove the term ''Alternative Security Programs'' and add, in its place, the term ''ASPs''; and
■ b. In paragraph (b) remove the term ''SVA'' wherever it appears, and add, in its place, the term ''Security Vulnerability Assessment''.

§ 27.245 [Amended]

■ 18. Amend § 27.245 as follows:
■ a. In paragraph (a)(1) introductory text:
■ i. Remove the phrase ''review and approve or disapprove all'' and add, in its place, the phrase ''review, and either approve or disapprove, all'';
■ ii. Remove the term ''Alternative Security Programs'' and add, in its place, the term ''ASPs'';
■ b. In paragraph (a)(1)(i) remove the phrase ''Upon receipt of Site Security Plan'' and add, in its place, the phrase ''Upon receipt of the Site Security Plan''; and
■ c. In paragraph (b) remove the term ''SSP'' wherever it appears and add, in its place, the term ''Site Security Plan''.

§ 27.250 [Amended]

■ 19. Amend § 27.250 as follows:
■ a. In paragraph (c)(1) remove the term ''Under Secretary or Assistant Secretary'' and add, in its place, the term ''Director or Executive Assistant Director'';
■ b. In paragraph (c)(2) remove the term ''Director of the Chemical Security Division'' and add, in its place, the term ''Associate Director for Chemical Security'';
■ c. In paragraph (d)(3) in the second sentence, remove the phrase ''object and electronically stored'' and add, in its place, the phrase ''objects, and electronically stored'';
■ d. In paragraph (e) remove the term ''CVI'' and add, in its place, the term ''Chemical-terrorism Vulnerability Information''; and
■ e. In paragraph (f) remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director''.

§ 27.255 [Amended]

■ 20. Amend § 27.255 as follows:
■ a. In paragraph (a)(1) remove the period at the end of the paragraph and add, in its place, a semicolon;
■ b. In paragraph (a)(2) add a comma after the term ''lessons learned''; and
■ c. In paragraph (a)(6) remove the period at the end of the paragraph and add, in its place ''; and''.

§ 27.300 [Amended]

■ 21. Amend § 27.300 as follows:
■ a. Remove the term ''Assistant Secretary'' wherever it appears and add, in its place, the term ''Executive Assistant Director'';
■ b. In paragraph (b)(1) remove the phrase ''the Assistant may enter an Order Assessing Civil Penalty'' and add, in its place, the phrase ''the Executive Assistant Director may enter an Order Assessing Civil Penalty'';
■ c. In paragraph (b)(2) add the word, ''the'' before the word ''Department'';
■ d. In paragraph (c)(1)(iv) remove the word ''and'' after the semicolon at the end of the paragraph;
■ e. In paragraph (c)(1)(v):
■ i. Remove the comma after the word ''statement''; and
■ ii. Remove the word ''chemical'' and add, in its place, the word ''facility'';
■ f. In paragraph (d) remove the term ''Notice for Application for Review'' and add, in its place, the term ''Notice of Application for Review''; and
■ g. In paragraph (f) remove the term ''Notice of Application of Review'' and add, in its place, the term ''Notice of Application for Review''.

§ 27.305 [Amended]

■ 22. Amend § 27.305(a) by removing the word ''which'' and add, in its place, the word ''that''.

§ 27.310 [Amended]

■ 23. Amend § 27.310 by:
■ a. Removing the terms ''Assistant Secretary'' and ''Assistant Secretary's'' wherever they appear and adding in their places the terms ''Executive Assistant Director'' and ''Executive Assistant Director's'', respectively;
■ b. In paragraph (b)(1) removing the phrase, ''with the office of the Department hereinafter designated by the Secretary'';
■ c. In paragraph (b)(3) removing the term ''General Counsel'' and adding, in its place, the term ''Office of the Chief Counsel'';
■ d. In paragraph (b)(5) removing the phrase ''fourteen calendar days'' and adding, in its place, the phrase ''14 calendar days''; and
■ e. In paragraph (c):
■ i. Removing the term ''Office of General Counsel'' and adding, in its place, the term ''Office of the Chief Counsel'';
■ ii. Adding a comma after the word ''affidavits''; and
■ iii. Removing the phrase ''fourteen calendar days'' and adding, in its place, the phrase ''14 calendar days''; and
■ f. In paragraph (d) introductory text, removing the phrase ''(as determined in his sole discretion)'' and adding, in its place, the phrase ''(as determined in his or her sole discretion)''.

§ 27.315 [Amended]

■ 24. Amend § 27.315(b) by removing the phrase ''this subpart, to serve generally in the capacity'' and adding, in its place, the phrase ''this subpart, to serve, generally, in the capacity''.

§ 27.320 [Amended]

■ 25. Amend § 27.320 by:
■ a. Removing the term ''*ex parte*'' wherever it appears and adding in its place the term ''ex parte''; and
■ b. In paragraph (b) removing the phrase ''which is relevant'' and adding, in its place, the phrase ''that is relevant''.

§ 27.325 [Amended]

■ 26. Amend § 27.325 by removing the term ''Assistant Secretary'' and adding, in its place, the term ''Executive Assistant Director''.

§ 27.330 [Amended]

■ 27. Amend § 27.330(b) by adding the word ''a'' before the phrase ''decision as a matter of law''.

§ 27.335 [Amended]

■ 28. Amend § 27.335 as follows:
■ a. In paragraph (b)(1) remove the word ''his'' wherever it appears and add, in its place, the phrase ''his or her''; and

■ b. In paragraph (b)(2):
■ i. Remove the phrase ''facility of other person'' and add, in its place, the phrase ''facility or other person'';
■ ii. Add a comma after the term ''direct testimony'';
■ iii. Remove the word ''he'' and add, in its place, the phrase ''he or she''; and
■ iv. Add a comma after the phrase ''administrative action''.

§ 27.345 [Amended]

■ 29. Amend § 27.345 by:
■ a. Removing the term ''Under Secretary'' wherever it appears and adding, in its place, the term ''Director'';
■ b. Removing the term ''Assistant Secretary'' wherever it appears and adding, in its place, the term ''Executive Assistant Director'';
■ c. In paragraph (b)(3) removing the phrase ''General Counsel'' and adding, in its place, the phrase ''Office of the Chief Counsel'';
■ d. In paragraph (d)(1) removing the phrase ''his designee'' and adding, in its place, the phrase ''his or her designee''; and
■ e. Removing the term ''*ex parte*'' wherever it appears in paragraphs (d)(1) through (d)(3), and adding in its place ''ex parte'';
■ f. In paragraph (d)(2):
■ i. Removing the phrase ''his designee'' wherever it appears, and adding, in its place, the phrase ''his or her designee'';
■ ii. Removing the phrase ''information which is relevant'' and adding, in its place, the phrase ''information that is relevant'';

■ 30. Amend § 27.400 by:
■ a. Removing the term ''Assistant Secretary'' wherever it appears and adding, in its place, the term ''Executive Assistant Director''
■ b. In paragraph (a):
■ i. Removing the phrase ''section 550(c) of the Homeland Security Appropriations Act of 2007'' and adding, in its place, the term ''6 U.S.C. 621 *et seq.*'';
■ ii. Adding a comma after the word ''State''; and
■ c. In paragraph (b) introductory text, removing the phrase ''section 550(c) of the Department of Homeland Security Appropriations Act of 2007'' and adding, in its place, the term ''6 U.S.C. 623'';
■ d. In paragraph (b)(3) adding a comma after the term ''Letters of Approval'';
■ e. In paragraph (b)(4) removing the word ''Alternate'' and adding in its place, the word ''Alternative'';
■ f. In paragraph (b)(7) adding a comma after the word ''notices'';
■ g. In paragraph (b)(9) after the word ''his'', adding the term ''or her'';
■ h. In paragraph (c)(1) adding the word ''and'' after the semicolon at the end of the paragraph;
■ i. In paragraph (d) introductory text removing the dash from the end of the paragraph and add in its place a colon.
■ j. In paragraph (d)(6) removing the dash from the end of the paragraph and adding in its place, a colon
■ k. In paragraph (d)(7) removing the period at the end of the paragraph and adding in its place, ''; and'';
■ l. In paragraph (d)(8):
■ i. Removing the term ''critical infrastructure information'' and adding in its place, the term ''Protected Critical Infrastructure Information'';
■ ii. Removing the term ''section 214 of the Homeland Security Act'' and adding in its place, the term ''6 U.S.C. 133''; and
■ iii. Removing the phrase ''section 214 and any implementing regulations'' and adding in its place, the phrase ''6 U.S.C. 133 and any implementing regulations'';
■ m. In paragraph (f)(1) introductory text removing the dash from end of the paragraph and adding in its place, a colon;
■ n. In paragraph (f)(2) revising the paragraph heading to read ''*Protective markings.*'';
■ o. In paragraph (f)(4) removing the term ''audio recording'' and adding in its place, the term ''audio recordings'';
■ p. In paragraph (g):
■ i. Revise the paragraph heading;
■ ii. Add a heading to paragraph (g)(1);
■ iii. In paragraph (g)(2), remove the first sentence and add a paragraph heading;
■ q. In paragraph (h)(1):
■ i. Removing the term ''section 550'' wherever it appears and adding, in its place, the term ''6 U.S.C. 621 *et seq.*''; and
■ ii. Removing the term ''his counsel'' and adding in its place, the term ''his or her counsel'';
■ r. In paragraph (i)(1) introductory text:
■ i. Removing the term ''section 550'' and adding, in its place, the term ''6 U.S.C. 621 *et seq.*''; and
■ ii. Removing the phrase ''his sole discretion'' and adding in its place the phrase ''his or her sole discretion'';
■ s. In paragraph (i)(2)introductory text:
■ i. Removing the term ''of section 550'' and adding in its place, the term ''under 6 U.S.C. 621 *et seq.*''; and
■ ii. Removing the dash from the end of the paragraph and adding in its place, a colon;
■ t. In paragraph (i)(6) removing the term ''of section 550'' and adding in its place, the term ''under 6 U.S.C. 621 *et seq.*'';
■ u. In paragraph (i)(7):
■ i. In the introductory text, removing the dash at the end of the sentence and adding a period;
■ ii. In paragraph (i)(7)(i) removing the word ''Objection—'' and adding a paragraph heading;
■ iii. In paragraph (i)(7)(ii) removing the words ''Action by court—'' and adding a paragraph heading; and
■ iv. In paragraph (i)(7)(iii) removing the words ''Obligation by defendant—'' and adding a paragraph heading; and
■ v. In paragraph (k)(1) removing the citation ''(5 U.S.C. 105)'' and adding, in its place, the citation ''(codified at 44 U.S.C. 3101 *et seq.* and 3301 *et seq.*)''.

The revision reads as follows:

§ 27.400 Chemical-terrorism vulnerability information.

* * * * *

(f) * * *

(2) *Protective markings.* * * *

* * * * *

(g) *Disclosure by the Department*—(1) *In general.* * * *

(2) Disclosure of Segregable Information under the Freedom of Information Act and the Privacy Act. * * *

* * * * *

(i) * * *

(7) * * *

(i) *Objection.* * * *

(ii) *Action by court.* * * *

(iii) *Obligation of defendant.* * * *

* * * * *

§ 27.405 [Amended]

■ 31. Amend § 27.405 as follows:
■ a. In paragraph (a) introductory text:
■ i. Remove the term ''state law'' and add, in its place, the term ''State law'';
■ ii. Add a comma after the phrase ''poses an obstacle to''; and
■ iii. Add a comma after the word ''disapproval'';
■ b. In paragraph (b):
■ i. Add a comma after the phrase ''State law, regulation'' wherever it appears; and
■ ii. Remove the phrase, ''promulgated regulation, ordinance, administrative action, order or decision, or common law standard'' and, in its place, add the phrase ''promulgated regulation, ordinance, administrative action, order, decision, or common law standard'';
■ c. In paragraph (c) remove the phrase ''regulation, or administrative action, or decision or'' and add, in its place, the phrase ''regulation, administrative action, decision, or'';
■ d. In paragraph (d)(1)
■ i. Remove the phrase ''administrative actions, or opinions or orders'' and add, in its place, the phrase ''administrative actions, opinions, or orders''; and
■ ii. Add a comma after the term ''pose an obstacle to''; and

■ e. In paragraph (d)(2) remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director''.

§ 27.410 [Amended]

■ 32. Amend § 27.410 as follows:

■ a. In the section heading, remove the term ''Third party'' and add, in its place, the term ''Third-party''; and

■ b. In paragraph (b) remove the term ''Assistant Secretary'' and add, in its place, the term ''Executive Assistant Director''.

Alejandro Mayorkas,

Secretary, Department of Homeland Security.

[FR Doc. 2021–14398 Filed 8–3–21; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0417; Airspace Docket No. 21–AGL–23]

RIN 2120–AA66

Amendment of Class E Airspace; Eveleth, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace extending upward from 700 feet above the surface at Eveleth-Virginia Municipal Airport, Eveleth, MN. This action is the result of an airspace review caused by the decommissioning of the Eveleth non-directional beacon (NDB). The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, October 7, 2021. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://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 7400.11E at NARA, email *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

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 the Class E airspace extending upward from 700 feet above the surface at Eveleth-Virginia Municipal Airport, Eveleth, MN, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (86 FR 28728; May 28, 2021) for Docket No. FAA–2021–0417 to amend the Class E airspace extending upward from 700 feet above the surface at Eveleth-Virginia Municipal Airport, Eveleth, MN. 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 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The 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 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface to within an 8.7-mile (increased from a 7-mile) radius of Eveleth-Virginia Municipal Airport, Eveleth, MN; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review caused by the decommissioning of the Eveleth NDB which provided navigation information for the instrument procedures at this airport.

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

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, is non-controversial and unlikely to result in adverse or negative comments. 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 5–6.5.a. 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.

List 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 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

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

* * * * *

AGL MN E5 Eveleth, MN [Amended]

Eveleth-Virginia Municipal Airport, MN (Lat. 47°25′27″ N, long. 92°29′48″ W)

That airspace extending upward from 700 feet above the surface within an 8.7-mile radius of the Eveleth-Virginia Municipal Airport.

Issued in Fort Worth, Texas, on July 29, 2021.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–16531 Filed 8–3–21; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0651; FRL–8623–01–OCSPP]

Zeta-Cypermethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of zeta-cypermethrin in or on multiple commodities that are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 4, 2021. Objections and requests for hearings must be received on or before October 4, 2021, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0651, is available online at *http://www.regulations.gov* or in-person at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

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

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2019–0651 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 4, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2019–0651, by one of the following methods:

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

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 15, 2020 (85 FR 20910) (FRL–10006–54), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8790) by IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested EPA to establish tolerances in 40 CFR part 180 for residues of zeta-cypermethrin (S-cyano(3-phenoxyphenyl) methyl (±))(cis-trans 3-(2,2-dichloroethenyl)-2,2 dimethylcyclopropanecarboxylate), including its metabolites and degradates, measuring only total cypermethrin, cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane carboxylate, in or on 116 separate commodities and to remove 52 established commodities upon establishment of the new commodities. Due to the length of the list of commodities, please refer to the Notice of Filing referenced above for a complete list of commodities to be established and removed. That document referenced a summary of the petition prepared by FMC, the registrant, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing some tolerances at different levels than were petitioned for and is also modifying some of the commodity definitions to be consistent with Agency nomenclature. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Type II pyrethroids, such as the cypermethrins (cypermethrin, zeta-cypermethrin, and alpha-cypermethrin), contain an alpha-cyano moiety, and in rats produce a syndrome that includes pawing, burrowing, salivation, hypothermia, and coarse tremors leading to choreoathetosis. The adverse outcome pathway (AOP) shared by pyrethroids involves the ability to interact with voltage-gated sodium channels (VGSCs) in the central and peripheral nervous system, leading to changes in neuron firing and, ultimately, neurotoxicity.

The toxicology database for the cypermethrins is considered complete with respect to guideline toxicity studies. While each active ingredient does not have its own complete database, studies have been bridged across the three chemicals and together are considered adequate for human health risk assessment. When evaluated together, the toxicity database for the cypermethrins can be used to characterize the overall suite of effects associated with cypermethrin exposure, including potential developmental and reproductive toxicity, immunotoxicity, and neurotoxicity.

The cypermethrins affect the nervous system, and neurotoxicity is the most sensitive effect observed throughout the toxicology database. Effects (clinical signs of neurotoxicity) were seen for all three compounds across species, sexes, and routes of administration. The endpoints and points of departure (PODs) selected for risk assessment are based on neurotoxicity and are protective of all toxic effects observed in the database.

There was no evidence of increased quantitative or qualitative susceptibility in the available rat and rabbit developmental toxicity studies and rat two-generation reproductive studies with the cypermethrins. A developmental neurotoxicity (DNT) study with zeta-cypermethrin indicated increased sensitivity in the offspring, based on body weight changes in pups in the absence of treatment-related effects in maternal animals at the highest dose tested. However, there is a clear NOAEL for effects seen in pups, and the doses and endpoints selected for risk assessment are protective of the susceptibility.

For pyrethroid chemicals, the pharmacokinetics indicate that the onset of neurotoxicity is rapid, with the time to peak effect for neurobehavioral effects occurring within hours. This is followed by rapid metabolism and elimination that does not result in accumulation. For the cypermethrins, the points of departure (PODs) for clinical signs after single or repeated exposure are comparable across durations of exposure. Thus, consistent with this class of compounds, neurotoxicity is not considered to progress with repeated exposure. Therefore, repeated dosing is essentially a series of acute exposures. As there is no apparent increase in hazard from repeated/chronic exposures to cypermethrins, the acute exposure assessment is protective of chronic exposures. The totality of the information suggests that only single day risk assessments need to be conducted for the cypermethrins.

Cypermethrin is classified as a Group C ''Possible human carcinogen,'' based on an increased incidence of benign lung adenomas and adenomas plus carcinomas combined in females in a mouse carcinogenicity study. No tumors were seen in cypermethrin cancer studies in rats or in a cancer study in mice with alpha-cypermethrin. The Agency has determined that quantification of cancer risk using a non-linear approach (*i.e.,* RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to the cypermethrins. While the Agency would typically use a chronic population adjusted dose (cPAD) to protect for cancer concerns, use of the acute population adjusted dose (aPAD) is considered protective because increasing toxicity with increasing

duration of exposure is not demonstrated for the cypermethrins. The NOAEL in the mouse cancer study is 57 mg/kg/day and tumors were seen at 229 mg/kg/day. The acute point of departure (POD) of 7.16 mg/kg/day selected for risk assessment is 32-fold lower than the dose that induced lung tumors in mice. Only the mouse study with cypermethrin resulted in tumor formation: No evidence of carcinogenicity was observed in cancer studies in rats with cypermethrin or mice with alpha-cypermethrin.

Specific information on the studies received and the nature of the adverse effects caused by zeta-cypermethrin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled ''Zeta-Cypermethrin, Human Health Risk Assessment for a Proposed Use on Basil and Various Crop Group Expansions and Conversions'' (hereinafter ''Zeta-Cypermethrin Human Health Risk Assessment'') on pages 45–51 in docket ID number EPA–HQ–OPP–2019–0651.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide.*

A summary of the toxicological endpoints for zeta-cypermethrin used for human risk assessment can be found in the Zeta-Cypermethrin Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to zeta-cypermethrin, EPA considered exposure under the petitioned-for tolerances as well as all existing tolerances for the cypermethrins in 40 CFR 180.418. EPA assessed dietary exposures from zeta-cypermethrin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

In conducting the acute dietary exposure assessment, EPA used the 2003–2008 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment is a refined probabilistic assessment based on tolerance level residues for most commodities and Pesticide Data Program (PDP) monitoring data for the commodities that make the most significant contribution to dietary risk. Estimates of the maximum percent crop treated were used for the same commodities for which PDP data were used and for one commodity for which the tolerance was used. Additional information on the assumptions used in the acute assessment can be found on pages 35–36 in the Zeta-Cypermethrin Human Health Risk Assessment.

ii. *Chronic exposure.* A chronic dietary risk assessment is not required for zeta-cypermethrin because repeated exposure does not result in a POD lower than that resulting from acute exposure. Therefore, the acute dietary risk assessment is protective of chronic dietary risk. However, EPA performed a chronic dietary exposure assessment for use in the aggregate assessment, since there are residential exposures for zeta-cypermethrin that need to be aggregated with background exposure from dietary sources. In the aggregate human health risk assessment, the average or chronic exposure estimates are combined with the appropriate residential exposure estimates and compared to the POD for zeta-cypermethrin.

The chronic dietary exposure assessment is a highly refined assessment based on Pesticide Data Program (PDP) monitoring data for most commodities. Tolerance level residues were used for a small number of commodities including fresh and dried basil; however, these commodities are not highly consumed and, therefore, they make a negligible contribution to the dietary risk. Refining the residue estimates for these commodities would have an insignificant effect on exposure estimates. As with the acute assessment, conservative default processing factors were generally used for the processed commodities for which they were available. The Agency made the conservative assumption that 100% of all commodities would be treated. When monitoring data were used, average residues were calculated by incorporating ½ limit of detection (LOD) values for all non-detects. No zeros were used to calculate the average residues. The cypermethrins have food handling establishment (FHE) uses that need to be accounted for in the chronic dietary exposure assessment. For these uses, EPA used a residue value of one-half the tolerance. BEAD provided an estimate of the probability that a food item a person consumes contains residues as a result of treatment in an FHE at some point with any pesticide. It is not specific to the cypermethrins. This estimate is 4.65%. In the chronic assessment, this value was used for the same commodities as the ones with the FHE residue value (0.025 ppm). In cases where the total anticipated residue from the FHE use exceeded the total anticipated residue from the agricultural use, the FHE anticipated residue was used.

iii. *Cancer.* Cypermethrin is classified as a Group C ''Possible human carcinogen,'' based on an increased incidence of benign lung adenomas and adenomas plus carcinomas combined in females in a mouse carcinogenicity study on cypermethrin. The Agency has determined that quantification of risk using a non-linear approach (*i.e.,* aPAD or aRfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to the cypermethrins.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins

as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the acute assessment, the following PCT assumptions were made:

Cypermethrin

The following maximum percent crop treated estimates were used in the acute dietary risk assessment for the following crops that are currently registered for cypermethrin: Lettuce, head: 5%; lettuce, leaf: 5%; broccoli: 10%; cabbage: 10%; cauliflower: 10%.

Zeta-Cypermethrin

The following maximum percent crop treated estimates were used in the acute dietary risk assessment for the following crops that are currently registered for zeta-cypermethrin: Lettuce, head: 75%; lettuce, leaf: 75%; spinach: 55%; celery: 60%; broccoli: 30%; cabbage: 45%; cauliflower: 25%; bean, green: 20%; tomato, puree: 20%; orange, juice: 55%; grapefruit, juice: 65%; peach: 10%; grape: 5%; rice: 15%; sugarcane: 2.5%.

Alpha-Cypermethrin

The following maximum percent crop treated estimates were used in the acute dietary risk assessment for the following crops that are currently registered for cypermethrin: Lettuce, head: 20%; lettuce, leaf: 20%; spinach: 2.5%; celery: 2.5%; broccoli: 2.5%; cabbage: 2.5%; cauliflower: 2.5%; bean, green: 2.5%; tomato, puree: 2.5%; orange, juice: 2.5%; grapefruit, juice: 2.5%; rice: 85%.

In the chronic assessment, the Agency made the conservative assumption of 100% crop treated for all commodities with established tolerances. However, PCT was effectively incorporated into the assessment through the use of monitoring data for some commodities, which reflect the PCT for commodities in commerce. For the FHE uses, EPA incorporated an estimate of the probability that a food item a person consumes contains residues as a result of treatment in an FHE at some point with any pesticide. This estimate is 4.65%, which is not specific to the cypermethrins. In the chronic assessment, EPA used this value for all commodities that do not have established tolerances. EPA also used this value when the total anticipated residue for a commodity was higher for the FHE use than it was for the agricultural use.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which zeta-cypermethrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for zeta-cypermethrin in drinking water. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Surface Water Concentration Calculator (SWCC) and the Pesticide Root Zone Model for Groundwater (PRZM–GW), for the acute dietary risk assessment, EPA used an estimated drinking water concentration (EDWC) of 3.5 ppb in the DEEM–FCID Model. For the chronic exposure assessment (used to determine background exposure from food and drinking water for the purpose of aggregate risk assessment), EPA used a value of 0.035 ppb for both direct and indirect water. The groundwater estimate of 0.0036 ppb was much lower than surface water residues; therefore, the Agency used the surface water EDWCs in the assessments. The use of the surface water values in the dietary exposure assessment is protective of potential exposure through groundwater sources of drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). The cypermethrins are registered for a variety of non-agricultural purposes including recreational sites (*i.e.,* golf courses, athletic fields); indoor residential/commercial/industrial sites/structural/perimeter and lawn uses; gardens and trees; as well as mosquito adulticide, termiticide, and pet uses. The current action does not add any new uses with residential exposures.

For assessing aggregate exposure to adults, the Agency used exposures from

the inhalation handler scenario from applying cypermethrin with a sprinkler can to home gardens. For assessing aggregate exposure to children, the Agency used exposures to children 1 to <2 years old (dermal and incidental oral) from post-application exposure to pets treated with the pet medallion/tag formulated with zeta-cypermethrin.

The PODs for the oral and dermal routes are based on the same effects: Therefore, for children, the oral and dermal routes can be combined. Since the levels of concern for incidental oral risk and inhalation risk are different (100 and 30), the aggregate risk index (ARI) approach was used to calculate aggregate exposure and risk for adults. An ARI ≥1 is not of concern.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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

The Agency has determined that the pyrethroids and pyrethrins share a common mechanism of toxicity *http://www.regulations.gov;* EPA–HQ–OPP–2008–0489–0006. As explained in that document, the members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. In 2011, after establishing a common mechanism grouping for the pyrethroids and pyrethrins, the Agency conducted a cumulative risk assessment (CRA) which is available at *http://www.regulations.gov;* EPA–HQ–OPP–2011–0746. In that document, the Agency concluded that cumulative exposures to pyrethroids (based on pesticidal uses registered at the time the assessment was conducted) did not present risks of concern. For information regarding EPA's efforts to evaluate the risk of exposure to this class of chemicals, refer to *https://www.epa.gov/ingredients-used-pesticide-products/pyrethrins-and-pyrethroids.*

Since the 2011 CRA, for each new pyrethroid and pyrethrin use, the Agency has conducted a screen to evaluate any potential impacts on the CRA prior to those uses being granted. The most recent screen, which takes into account the previous uses and the new use on basil, demonstrates that the new uses will not significantly impact the cumulative assessment because dietary exposures comprise only a minor contribution to the total pyrethroid exposure. Therefore, there are no cumulative risks of concern for the pyrethroids and pyrethrins.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* No evidence of increased qualitative or quantitative susceptibility was noted in the developmental toxicity or reproduction studies for the cypermethrins. However, quantitative susceptibility was seen in the rat developmental neurotoxicity (DNT) study with zeta-cypermethrin with an increased sensitivity in the offspring based on body weight changes in pups (5–10%) in the absence of adverse, treatment-related effects in maternal animals. The results from the DNT study are very similar to results observed in the reproduction studies where body weight (BW) changes (decreased BW gain) were seen in maternal and offspring animals at doses similar to those in the DNT study, with no indication of increased susceptibility. Therefore, there is no residual concern for effects observed in the study and a clear developmental NOAEL and LOAEL were identified.

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

i. The toxicity database for the cypermethrins is complete.

ii. Like other pyrethroids, the cypermethrins cause neurotoxicity by interacting with sodium channels, leading to clinical signs of neurotoxicity. These effects are well characterized and adequately assessed by the available guideline and non-guideline studies. There are no residual uncertainties with regard to evidence of neurotoxicity for the cypermethrins.

iii. No evidence of increased qualitative or quantitative susceptibility was noted in the developmental toxicity or reproduction studies for the cypermethrins. However, quantitative susceptibility was seen in the rat developmental neurotoxicity (DNT) study, but for the reasons discussed in Unit III.D.2, there is no residual concern for effects observed in the study and a clear developmental NOAEL and LOAEL were identified.

iv. There are no residual uncertainties identified in the exposure databases. The dietary exposure assessments account for parent and metabolites of concern. The assessments include percent crop treated assumptions and conservative, default processing factors. Furthermore, conservative, upper-bound assumptions were used to determine exposure through drinking water and residential sources, such that these exposures have not been underestimated.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to zeta-cypermethrin from food and water will utilize 35% of the aPAD for adults 20 to 49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* A chronic dietary risk assessment is not required for zeta-cypermethrin because repeated exposure does not result in a POD lower than that resulting from acute exposure. Therefore, the acute dietary risk assessment is protective of chronic dietary risk.

3. *Short-term risk.* Short-term aggregate exposure takes into account

short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Zeta-cypermethrin is registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to zeta-cypermethrin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 140 for children and an ARI of 4.7 for adults. Because EPA's level of concern for zeta-cypermethrin is an MOE of 100 or below, or an ARI of 1 or below, these MOEs/ARIs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). While there is potential intermediate-term residential exposure, because the single dose and repeat dosing cypermethrin studies show that repeat exposures do not result in lower points of departure, the residential assessments are conducted as a series of acute exposures and the same endpoint is used regardless of duration. Therefore, the short-term aggregate assessment is considered protective of any intermediate-term exposures.

5. *Aggregate cancer risk for U.S. population.* EPA has classified zeta-cypermethrin as a ''possible human carcinogen'' and determined that a non-linear approach should be used for cancer assessment. As the acute dietary exposure estimates are not of concern, cancer risk is not of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to zeta-cypermethrin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate tolerance-enforcement methods are available in *PAM Volume II* for determining residues of zeta-cypermethrin in plant (Method I) and livestock (Method II) commodities. Both methods are gas chromatographic methods with electron-capture detection (GC/ECD). These methods are not stereospecific; therefore, no distinction is made between residues of cypermethrin (all 8 stereoisomers), zeta-cypermethrin (enriched in 4 isomers) and alpha-cypermethrin (enriched in 2 isomers).

B. International Residue Limits

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

There is no Codex MRL for cypermethrin or the enriched forms, alpha- and zeta-cypermethrin, in/on basil. There are, however, Codex MRLs for numerous commodities contained in the crop groups and subgroups for which tolerances are being established in this rulemaking. EPA is harmonizing the tolerances with Codex MRLs for teff, grain; tomato; the commodities in the fruit, stone group 12–12, fruit, citrus subgroups 10–10A, 10–10B, and 10–10C, and the nut, tree, group 14–12; edible podded beans and peas; and dried beans and peas.

EPA is not harmonizing several U.S. tolerances with corresponding Codex MRLs because the Codex MRLs are lower than the U.S. tolerances. The available residue data indicate that use under registered U.S. pesticide products would exceed the Codex MRLs and thus harmonizing could result in food being adulterated when following approved label instructions. EPA does not consider the lack of harmonization in these instances to provide a trade barrier to imports since commodities that comply with the Codex MRL could be imported into the United States. The U.S. tolerances that are not being harmonized for this reason are onion, bulb, subgroup 3–07A; onion, green, subgroup 3–07B; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F; rapeseed, subgroup 20A; sunflower, subgroup 20B; cottonseed, subgroup 20C; quinoa, grain; leafy greens subgroup 4–16A; *Brassica,* leafy greens, subgroup 4–16B; vegetable, *Brassica,* head and stem, group 5–16; fruit, pome, group 11–10; and kohlrabi.

In addition, EPA is establishing tolerances for the fruiting vegetable crop group 8–10, which includes tomato, bell pepper, nonbell pepper, eggplant, and okra, at 0.2 ppm because the available representative commodity data support establishing the crop group at 0.2 ppm. While this action harmonizes with the Codex MRL for tomato, it results in tolerance levels for the other commodities in the crop group being different from the Codex MRLs for other commodities in that group since Codex has established different levels for the different commodities. EPA has determined it is appropriate to maintain the crop group based on the representative commodity data supporting the group tolerance. Finally, EPA is not harmonizing tolerances for succulent shelled beans and peas commodities with the Codex MRLs for such commodities because the magnitude of the difference is too great. The current tolerance for the subgroup is 0.1 ppm, versus the Codex MRL of 0.7 ppm. In addition, the U.S. tolerance is currently harmonized with the Canadian MRL of 0.1 ppm for succulent shelled peas.

C. Response to Comments

One comment was received in response to the Notice of Filing. The comment stated in part that the Agency should ''deny ir4 rutgers chemical profiteering college from getting a permit.'' Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the zeta-cypermethrin tolerances are safe. The commenter has provided no information indicating that a safety determination cannot be supported.

D. Revisions to Petitioned-For Tolerances

Commodity definitions have been corrected to be consistent with Agency nomenclature. Also, EPA is not establishing a tolerance for edible podded pea as requested because the commodity is being removed from the proposed crop group 6–19. Edible podded pea is being removed from proposed crop group 6–19 because it is not referring to any specific pea.

The petitioner requested a tolerance of 0.7 ppm for the individual commodities in the proposed revisions to crop subgroup 6B, succulent shelled pea and bean subgroup. EPA is not revising the level of the individual tolerances because the magnitude of the difference is too great. The current tolerance for the subgroup is 0.1 ppm. In addition, the U.S. tolerance is currently harmonized with the Canadian MRL of 0.1 ppm for succulent shelled peas.

The petitioner requested a tolerance of 0.35 ppm for fruit, citrus, group 10–10. Codex has established MRLs of 0.3 ppm for citrus except pummelo and shaddock, and 0.5 ppm for the pummelo and grapefruits subgroup (including shaddock-like hybrids among other grapefruits). The 0.3 ppm Codex MRL is based on U.S. residue data. As a result, the Agency is establishing a tolerance of 0.3 ppm for the orange subgroup 10–10A and the lemon/lime subgroup 10–10B. The Agency is also establishing a tolerance of 0.5 ppm for the grapefruit subgroup 10–10C to harmonize with the Codex MRL of 0.5 ppm for the pummelo and grapefruits subgroup.

The petitioner requested a tolerance of 0.2 ppm for teff, grain. There is a Codex MRL of 0.3 ppm for Cereal grains except rice, barley, oats, rye, and wheat. The Codex cereal grains crop group includes teff. As a result, EPA is setting the tolerance on teff, grain at 0.3 ppm to harmonize with Codex.

E. International Trade Considerations

In this rule, EPA is establishing a lower tolerance for zeta-cypermethrin residues in or on the orange subgroup 10–10–A and the lemon/lime subgroup 10–10B than the current tolerance. The current tolerance for the fruit, citrus, group 10 is 0.35 ppm. For the reasons explained in Unit IV.D of this document (*i.e.,* to harmonize with the Codex MRLs), the Agency believes these revised, lower tolerances are appropriate.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of the changes to these tolerances in order to satisfy its obligations under the Agreement. In addition, the SPS Agreement requires that Members provide a ''reasonable interval'' between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. Accordingly, EPA is establishing an expiration date for the existing tolerance to allow this tolerance to remain in effect for a period of six months after the effective date of this final rule. After the 6-month period expires, this tolerance will be reduced or revoked, as indicated in the regulatory text, and allowable residues on fruit, citrus, group 10 must conform to the tolerance for subgroups 10–10A and 10–10B.

This reduction in tolerance level is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance level is supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of zeta-cypermethrin in or on the following commodities: Basil, dried leaves at 40 ppm; Basil, fresh leaves at 7 ppm; Bean, adzuki, dry seed at 0.05 ppm; Bean, American potato, dry seed at 0.05 ppm; Bean, asparagus, dry seed at 0.05 ppm; Bean, asparagus, edible podded at 0.7 ppm; Bean, black, dry seed at 0.05 ppm; Bean, broad, dry seed at 0.05 ppm; Bean, broad, succulent shelled at 0.1 ppm; Bean, catjang, edible podded at 0.7 ppm; Bean, catjang, dry seed at 0.05 ppm; Bean, catjang, succulent shelled at 0.1 ppm; Bean, cranberry, dry seed at 0.05 ppm; Bean, dry, dry seed at 0.05 ppm; Bean, field, dry seed at 0.05 ppm; Bean, French, dry seed at 0.05 ppm; Bean, French, edible podded at 0.7 ppm; Bean, garden, dry seed at 0.05 ppm; Bean, garden, edible podded at 0.7 ppm; Bean, goa, dry seed at 0.05 ppm; Bean, goa, edible podded at 0.7 ppm; Bean, goa, succulent shelled at 0.1 ppm; Bean, great northern, dry seed at 0.05 ppm; Bean, green, dry seed at 0.05 ppm; Bean, green, edible podded at 0.7 ppm; Bean, guar, dry seed at 0.05 ppm; Bean, guar, edible podded at 0.7 ppm; Bean, kidney, dry seed at 0.05 ppm; Bean, kidney, edible podded at 0.7 ppm; Bean, lablab, dry seed 0.05 ppm; Bean, lablab, edible podded 0.7 ppm; Bean, lablab, succulent shelled at 0.1 ppm; Bean, lima, dry seed at 0.05 ppm; Bean, lima, succulent shelled at 0.1 ppm; Bean, morama, dry seed at 0.05 ppm; Bean, moth, dry seed at 0.05 ppm; Bean, moth, edible podded at 0.7 ppm; Bean, moth, succulent shelled at 0.1 ppm; Bean, mung, dry seed at 0.05 ppm; Bean, mung, edible podded at 0.7 ppm; Bean, navy, dry seed at 0.05 ppm; Bean, navy, edible podded at 0.7 ppm; Bean, pink, dry seed at 0.05 ppm; Bean, pinto, dry seed at 0.05 ppm; Bean, red, dry seed at 0.05 ppm; Bean, rice, dry seed at 0.05 ppm; Bean, rice, edible podded at 0.7 ppm; Bean, scarlet runner, dry seed at 0.05 ppm; Bean, scarlet runner, edible podded at 0.7 ppm; Bean, scarlet runner, succulent shelled at 0.1 ppm; Bean, snap, edible podded at 0.7 ppm; Bean, sword, dry seed at 0.05 ppm; Bean, sword, edible podded at 0.7 ppm; Bean, tepary, dry seed at 0.05 ppm; Bean, urd, dry seed at 0.05 ppm; Bean, urd, edible podded at 0.7 ppm; Bean, wax, edible podded at 0.7 ppm; Bean, wax, succulent shelled at 0.1 ppm; Bean, yardlong, dry seed at 0.05 ppm; Bean, yardlong, edible podded at 0.7 ppm; Bean, yellow, dry seed at 0.05 ppm; *Brassica,* leafy greens, subgroup 4–16B at 14 ppm; Bushberry subgroup 13–07B at 0.8 ppm; Caneberry subgroup 13–07A at 0.8 ppm; Celtuce at 10 ppm; Chickpea, dry seed at 0.05 ppm; Chickpea, edible podded at 0.7 ppm; Chickpea, succulent shelled at 0.1 ppm; Cottonseed subgroup 20C at 0.5 ppm; Cowpea, dry seed at 0.05 ppm; Cowpea, edible podded at 0.7 ppm; Cowpea, succulent shelled at 0.1 ppm; Fennel, Florence, fresh leaves and stalk at 10 ppm; Fruit, pome, group 11–10 at 2 ppm; Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 2 ppm; Fruit, stone, group 12–12 at 2 ppm; Gram, horse, dry seed at 0.05 ppm; Grapefruit subgroup 10–10C at 0.5 ppm; Grass pea, dry seed at 0.05 ppm; Grass pea, edible podded at 0.7 ppm; Jackbean, dry seed at 0.05 ppm; Jackbean, edible podded at 0.7 ppm; Jackbean, succulent shelled at 0.1 ppm; Kohlrabi at 2 ppm; Leaf petiole vegetable subgroup 22B at 10 ppm; Leafy greens subgroup 4–16A at 10 ppm; Lemon/Lime subgroup 10–10B at 0.3 ppm; Lentil, dry seed at 0.05 ppm; Lentil, edible podded at 0.7 ppm; Lentil, succulent shelled at 0.1 ppm; Longbean, Chinese, dry seed at 0.05 ppm; Longbean, Chinese, edible podded at 0.7 ppm; Lupin, Andean, dry seed at 0.05 ppm; Lupin, Andean, succulent shelled at 0.1 ppm; Lupin, blue, dry seed at 0.05 ppm; Lupin, blue, succulent shelled at 0.1 ppm; Lupin, grain, dry seed at 0.05 ppm; Lupin, grain, succulent shelled at 0.1 ppm; Lupin, sweet white, dry seed at 0.05 ppm; Lupin, sweet white, succulent shelled at 0.1 ppm; Lupin, sweet, dry seed at 0.05 ppm; Lupin, sweet, succulent shelled at 0.1 ppm; Lupin, white, dry seed at 0.05 ppm; Lupin, white, succulent shelled at 0.1 ppm; Lupin, yellow, dry seed at 0.05 ppm; Lupin, yellow, succulent shelled at 0.1 ppm; Nut, tree, group 14–12 at 0.05 ppm; Onion, bulb, subgroup 3–07A at 0.1 ppm; Onion, green, subgroup 3–07B at 3 ppm; Orange subgroup 10–10A at 0.3 ppm; Pea, blackeyed, dry seed at 0.05 ppm; Pea, blackeyed, succulent shelled at 0.1 ppm; Pea, crowder, dry seed at 0.05 ppm; Pea, crowder, succulent shelled at 0.1 ppm; Pea, dry,

dry seed at 0.05 ppm; Pea, dwarf, edible podded at 0.7 ppm; Pea, English, succulent shelled at 0.1 ppm; Pea, field, dry seed at 0.05 ppm; Pea, garden, dry seed at 0.05 ppm; Pea, garden, succulent shelled at 0.1 ppm; Pea, green, dry seed at 0.05 ppm; Pea, green, edible podded at 0.7 ppm; Pea, green, succulent shelled at 0.1 ppm; Pea, pigeon, dry seed at 0.05 ppm; Pea, pigeon, edible podded at 0.7 ppm; Pea, pigeon, succulent shelled at 0.1 ppm; Pea, snap, edible podded at 0.7 ppm; Pea, snow, edible podded at 0.7 ppm; Pea, southern, dry seed at 0.05 ppm; Pea, southern, succulent shelled at 0.1 ppm; Pea, sugar snap, edible podded at 0.7 ppm; Pea, winged, dry seed at 0.05 ppm; Pea, winged, edible podded at 0.7 ppm; Quinoa, grain at 3 ppm; Quinoa, hay at 6 ppm; Quinoa, straw at 20 ppm; Rapeseed subgroup 20A at 0.2 ppm; Soybean, vegetable, dry seed at 0.05 ppm; Soybean, vegetable, edible podded at 0.7 ppm; Soybean, vegetable, succulent shelled at 0.1 ppm; Sunflower subgroup 20B at 0.2 ppm; Teff, forage 3 ppm; Teff, grain at 0.3 ppm; Teff, hay at 6 ppm; Teff, straw at 7 ppm; Vegetable, brassica, head and stem, group 5–16 at 2 ppm; Vegetable, fruiting, group 8–10 at 0.2 ppm; Velvetbean, dry seed at 0.05 ppm; Velvetbean, edible podded at 0.7 ppm; Velvetbean, succulent shelled at 0.1 ppm; and Yam bean, African, dry seed at 0.05 ppm.

Tolerances are also removed for the following commodities due to establishment of tolerances for the above commodities: Berry group 13 at 0.8 ppm; Borage, seed at 0.2 ppm; *Brassica,* head and stem, subgroup 5A at 2.00 ppm; *Brassica,* leafy greens, subgroup 5B at 14.00 ppm; Cabbage at 2.00 ppm; Castor oil plant, seed at 0.2 ppm; Chinese tallowtree, seed at 0.2 ppm; Cilantro, leaves at 10 ppm; Cotton, undelinted seed at 0.5 ppm; Crambe, seed at 0.2 ppm; Cuphea, seed at 0.2 ppm; Echium, seed at 0.2 ppm; Euphorbia, seed at 0.2 ppm; Evening primrose, seed at 0.2 ppm; Flax, seed at 0.2 ppm; Fruit, citrus, group 10 at 0.35 ppm; Fruit, pome, group 11 at 2 ppm; Fruit, stone, group 12 at 1 ppm; Gold of pleasure, seed at 0.2 ppm; Grape at 2 ppm; Hare's-ear mustard, seed at 0.2 ppm; Jojoba, seed at 0.2 ppm; Lesquerella, seed at 0.2 ppm; Lunaria, seed at 0.2 ppm; Meadowfoam, seed at 0.2 ppm; Milkweed, seed at 0.2 ppm; Mustard, seed at 0.2 ppm; Niger seed, seed at 0.2 ppm; Nut, tree, group 14 at 0.05 ppm; Oil radish, seed at 0.2 ppm; Okra at 0.2 ppm; Onion, bulb at 0.10 ppm; Onion, green at 3.00 ppm; Pea and bean, dried shelled, except soybean subgroup 6C at 0.05 ppm; Pea and bean, succulent shelled, subgroup 6B at 0.1 ppm; Pecan at 0.05 ppm; Pistachio at 0.05 ppm; Poppy, seed at 0.2 ppm; Rapeseed at 0.2 ppm; Rose hip, seed at 0.2 ppm; Safflower, seed at 0.2 ppm; Sesame, seed at 0.2 ppm; Stokes aster, seed at 0.2 ppm; Sunflower, seed at 0.2 ppm; Sweet rocket, seed at 0.2 ppm; Tallowwood, seed at 0.2 ppm; Tea oil plant, seed at 0.2 ppm; Turnip, greens at 14 ppm; Vegetable, fruiting, group 8 at 0.2 ppm; Vegetable, leafy, except brassica, group 4 at 10.00 ppm; Vegetable, legume, edible podded, subgroup 6A at 0.5 ppm; and Vernonia, seed at 0.2 ppm.

In addition, EPA is removing language from paragraph (a)(3) for tolerances that have expired. The tolerances for residues of alpha-cypermethrin on ''Fruit, citrus, group 10–10'' at 10 ppm and ''Hog, fat'' at 1.0 ppm expired on December 5, 2018, as indicated by the footnote associated with those entries in the table in paragraph (a)(3). EPA is removing those expired tolerances as part of this rule as a housekeeping measure.

VI. Statutory and Executive Order Reviews

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

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

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

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

VII. Congressional Review Act (CRA)

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

List of Subjects in 40 CFR Part 180

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

Dated: July 22, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

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

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

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

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

■ 2. In § 180.418:

■ a. Amend paragraph (a)(2) by revising the table; and

■ b. Amend the table in paragraph (a)(3) by:

■ i. Adding the heading ''Table 3 to Paragraph (a)(3)'';

■ ii. Removing the entries ''Fruit, citrus, group 10–10 [1]'' and ''Hog, fat [1]''; and

■ iii. Removing the corresponding footnote 1.

The additions and revisions read as follows:

§ 180.418 Cypermethrin and isomers alpha-cypermethrin and zeta-cypermethrin; tolerances for residues.

* * * * *

(a)(2) * * *

TABLE 2 TO PARAGRAPH (a)(2)

Commodity	Parts per million
Alfalfa, forage	15
Alfalfa, hay	30
Alfalfa, seed	0.50
Almond, hulls	6
Animal feed, nongrass, group 18, forage	8
Animal feed, nongrass, group 18, hay	40
Artichoke, globe	0.60
Avocado	0.50
Barley, grain	3.0
Barley, hay	6.0
Barley, straw	20.0
Basil, dried leaves	40
Basil, fresh leaves	7
Bean, adzuki, dry seed	0.05
Bean, American potato, dry seed	0.05
Bean, asparagus, dry seed	0.05
Bean, asparagus, edible podded	0.7
Bean, black, dry seed	0.05
Bean, broad, dry seed	0.05
Bean, broad, succulent shelled	0.1
Bean, catjang, dry seed	0.05
Bean, catjang, edible podded	0.7
Bean, catjang, succulent shelled	0.1
Bean, cranberry, dry seed	0.05
Bean, dry, dry seed	0.05
Bean, field, dry seed	0.05
Bean, French, dry seed	0.05
Bean, French, edible podded	0.7
Bean, garden, dry seed	0.05
Bean, garden, edible podded	0.7
Bean, goa, dry seed	0.05
Bean, goa, edible podded	0.7
Bean, goa, succulent shelled	0.1
Bean, great northern, dry seed	0.05
Bean, green, dry seed	0.05
Bean, green, edible podded	0.7
Bean, guar, dry seed	0.05
Bean, guar, edible podded	0.7
Bean, kidney, dry seed	0.05
Bean, kidney, edible podded	0.7
Bean, lablab, dry seed	0.05
Bean, lablab, edible podded	0.7
Bean, lablab, succulent shelled	0.1
Bean, lima, dry seed	0.05
Bean, lima, succulent shelled	0.1
Bean, morama, dry seed	0.05
Bean, moth, dry seed	0.05
Bean, moth, edible podded	0.7
Bean, moth, succulent shelled	0.1
Bean, mung, dry seed	0.05
Bean, mung, edible podded	0.7
Bean, navy, dry seed	0.05
Bean, navy, edible podded	0.7
Bean, pink, dry seed	0.05
Bean, pinto, dry seed	0.05
Bean, red, dry seed	0.05
Bean, rice, dry seed	0.05
Bean, rice, edible podded	0.7
Bean, scarlet runner, dry seed	0.05
Bean, scarlet runner, edible podded	0.7

TABLE 2 TO PARAGRAPH (a)(2)—Continued

Commodity	Parts per million
Bean, scarlet runner, succulent shelled	0.1
Bean, snap, edible podded	0.7
Bean, sword, dry seed	0.05
Bean, sword, edible podded	0.7
Bean, tepary, dry seed	0.05
Bean, urd, dry seed	0.05
Bean, urd, edible podded	0.7
Bean, wax, edible podded	0.7
Bean, wax, succulent shelled	0.1
Bean, yardlong, dry seed	0.05
Bean, yardlong, edible podded	0.7
Bean, yellow, dry seed	0.05
Beet, sugar, roots	0.05
Beet, sugar, tops	0.20
Brassica, leafy greens, subgroup 4–16B	14
Buckwheat, grain	3.0
Buckwheat, hay	6.0
Buckwheat, straw	20.0
Bushberry subgroup 13–07B	0.8
Caneberry subgroup 13–07A	0.8
Canistel	0.50
Castor oil plant, refined oil	0.4
Cattle, fat	1.00
Cattle, meat	0.2
Cattle, meat byproducts	0.05
Celtuce	10
Chickpea, dry seed	0.05
Chickpea, edible podded	0.7
Chickpea, succulent shelled	0.1
Chinese tallowtree, refined oil	0.4
Citrus, dried pulp	1.8
Citrus, oil	4.0
Corn, field, forage	9.0
Corn, field, grain	0.05
Corn, field, stover	30
Corn, pop, grain	0.05
Corn, pop, stover	30
Corn, sweet, forage	15.00
Corn, sweet, kernel plus cob with husks removed	0.05
Corn, sweet, stover	15.00
Cottonseed subgroup 20C	0.5
Cowpea, dry seed	0.05
Cowpea, edible podded	0.7
Cowpea, succulent shelled	0.1
Egg	0.05
Euphorbia, refined oil	0.4
Evening primrose, refined oil	0.4
Fennel, Florence, fresh leaves and stalk	10
Food commodities/feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments	0.05
Fruit, citrus, group 10 [1]	0.35
Fruit, pome, group 11–10	2
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F	2
Fruit, stone, group 12–12	2
Goat, fat	1.00
Goat, meat	0.2
Goat, meat byproducts	0.05
Grain, aspirated fractions	10.0
Gram, horse, dry seed	0.05
Grapefruit subgroup 10–10C	0.5
Grass, forage, fodder, and hay, group 17, forage	10
Grass, forage, fodder and hay, group 17, hay	35
Grass pea, dry seed	0.05
Grass pea, edible podded	0.7
Hog, fat	0.1
Hog, meat	0.05
Horse, fat	1.00
Horse, meat	0.2
Horse, meat byproducts	0.05
Jackbean, dry seed	0.05
Jackbean, edible podded	0.7

TABLE 2 TO PARAGRAPH (a)(2)—Continued

Commodity	Parts per million
Jackbean, succulent shelled	0.1
Jojoba, refined oil	0.4
Kohlrabi	2
Leaf petiole vegetable subgroup 22B	10
Leafy greens subgroup 4–16A	10
Lemon/Lime subgroup 10–10B	0.3
Lentil, dry seed	0.05
Lentil, edible podded	0.7
Lentil, succulent shelled	0.1
Longbean, Chinese, dry seed	0.05
Longbean, Chinese, edible podded	0.7
Lupin, Andean, dry seed	0.05
Lupin, Andean, succulent shelled	0.1
Lupin, blue, dry seed	0.05
Lupin, blue, succulent shelled	0.1
Lupin, grain, dry seed	0.05
Lupin, grain, succulent shelled	0.1
Lupin, sweet white, dry seed	0.05
Lupin, sweet white, succulent shelled	0.1
Lupin, sweet, dry seed	0.05
Lupin, sweet, succulent shelled	0.1
Lupin, white, dry seed	0.05
Lupin, white, succulent shelled	0.1
Lupin, yellow, dry seed	0.05
Lupin, yellow, succulent shelled	0.1
Mango	0.70
Milk, fat (reflecting 0.10 in whole milk)	2.50
Niger seed, refined oil	0.4
Nut, tree, group 14–12	0.05
Oat, grain	3.0
Oat, hay	6.0
Oat, straw	20.0
Onion, bulb, subgroup 3–07A	0.1
Onion, green, subgroup 3–07B	3
Orange subgroup 10–10A	0.3
Papaya	0.50
Pea, blackeyed, dry seed	0.05
Pea, blackeyed, succulent shelled	0.1
Pea, crowder, dry seed	0.05
Pea, crowder, succulent shelled	0.1
Pea, dry, dry seed	0.05
Pea, dwarf, edible podded	0.7
Pea, English, succulent shelled	0.1
Pea, field, dry seed	0.05
Pea, garden, dry seed	0.05
Pea, garden, succulent shelled	0.1
Pea, green, dry seed	0.05
Pea, green, edible podded	0.7
Pea, green, succulent shelled	0.1
Pea, pigeon, dry seed	0.05
Pea, pigeon, edible podded	0.7
Pea, pigeon, succulent shelled	0.1
Pea, snap, edible podded	0.7
Pea, snow, edible podded	0.7
Pea, southern, dry seed	0.05
Pea, southern, succulent shelled	0.1
Pea, sugar snap, edible podded	0.7
Pea, winged, dry seed	0.05
Pea, winged, edible podded	0.7
Peanut	0.05
Poultry, fat	0.05
Poultry, meat	0.05
Quinoa, grain	3
Quinoa, hay	6
Quinoa, straw	20
Rapeseed subgroup 20A	0.2
Rice, grain	1.50
Rice, hulls	6.00
Rice, wild, grain	1.5
Rose hip, refined oil	0.4
Rye, grain	3.0

TABLE 2 TO PARAGRAPH (a)(2)—Continued

Commodity	Parts per million
Rye, hay	6.0
Rye, straw	20.0
Sapodilla	0.50
Sapote, black	0.50
Sapote, mamey	0.50
Sheep, fat	1.00
Sheep, meat	0.2
Sheep, meat byproducts	0.05
Sorghum, grain, forage	0.1
Sorghum, grain, grain	0.5
Sorghum, grain, stover	5.0
Soybean, seed	0.05
Soybean, vegetable, dry seed	0.05
Soybean, vegetable, edible podded	0.7
Soybean, vegetable, succulent shelled	0.1
Star apple	0.50
Stokes aster, refined oil	0.4
Sugarcane, cane	0.60
Sunflower subgroup 20B	0.2
Sunflower, refined oil	0.5
Tallowwood, refined oil	0.4
Tea oil plant, refined oil	0.4
Teff, forage	3
Teff, grain	0.3
Teff, hay	6
Teff, straw	7
Vegetable, brassica, head and stem, group 5–16	2
Vegetable, cucurbit, group 9	0.2
Vegetable, fruiting, group 8–10	0.2
Vegetable, root and tuber, group 1, except sugar beet	0.1
Velvetbean, dry seed	0.05
Velvetbean, edible podded	0.7
Velvetbean, succulent shelled	0.1
Vernonia, refined oil	0.4
Wheat, forage	3.0
Wheat, grain	0.2
Wheat, hay	6.0
Wheat, straw	7.0
Yam bean, African, dry seed	0.05

[1] This tolerance expires on February 4, 2022.

(a)(3) * * *

Table 3 to Paragraph (a)(3)

* * * * *

[FR Doc. 2021–16189 Filed 8–3–21; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 86, No. 147
Wednesday, August 4, 2021

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF LABOR

Office of the Secretary of Labor

29 CFR Parts 10 and 23

RIN 1235–AA41

Increasing the Minimum Wage for Federal Contractors

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Proposed rulemaking; extension of comment period.

SUMMARY: This document extends the period for submitting written comments on the Notice of Proposed Rulemaking (NPRM), ''Increasing the Minimum Wage for Federal Contractors.'' The comment period now ends on August 27, 2021. The Department of Labor (Department) is taking this action to provide interested parties additional time to submit comments in response to a request to extend the comment period.

DATES: The comment period for the proposed rule published July 22, 2021, at 86 FR 38816, is extended. Comments must be received on this notice of proposed rulemaking on or before August 27, 2021.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 1235–AA41, by either of the following methods: *Electronic Comments:* Submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. *Mail:* Address written submissions to Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210. *Instructions:* Please submit only one copy of your comments by only one method. Commenters submitting file attachments on *www.regulations.gov* are advised that uploading text-recognized documents—*i.e.,* documents in a native file format or documents which have undergone optical character recognition (OCR)—enable staff at the Department to more easily search and retrieve specific content included in your comment for consideration. Anyone who submits a comment (including duplicate comments) should understand and expect that the comment will become a matter of public record and will be posted without change to *https://www.regulations.gov,* including any personal information provided. The Wage and Hour Division (WHD) posts comments gathered and submitted by a third-party organization as a group under a single document ID number on *https://www.regulations.gov.* Comments must be received by 11:59 p.m. on August 27, 2021 for consideration in this rulemaking. Commenters should transmit comments early to ensure timely receipt prior to the close of the comment period, as the Department continues to experience delays in the receipt of mail. Submit only one copy of your comments by only one method. *Docket:* For access to the docket to read background documents or comments, go to the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Amy DeBisschop, Director of the Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210, telephone: (202) 693–0406 (this is not a toll-free number). *Accessible Format:* Copies of this notice of proposed rulemaking may be obtained in alternative formats (Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, large print, braille, audiotape, compact disc, or other accessible format), upon request, by calling (202) 693–0675 (this is not a toll-free number). TTY/TDD callers may dial toll-free (877) 889–5627 to obtain information or request materials in alternative formats.

Questions of interpretation or enforcement of the agency's existing regulations may be directed to the nearest WHD district office. Locate the nearest office by calling the WHD's toll-free help line at (866) 4US–WAGE ((866) 487–9243) between 8 a.m. and 5 p.m. in your local time zone, or log onto WHD's website at *https://www.dol.gov/agencies/whd/contact/local-offices* for a nationwide listing of WHD district and area offices.

SUPPLEMENTARY INFORMATION:

I. Background

On April 27, 2021, President Joseph R. Biden Jr. issued Executive Order 14026, ''Increasing the Minimum Wage for Federal Contractors.'' This Executive order explains that increasing the hourly minimum wage paid to workers performing on or in connection with covered federal contracts to $15.00 beginning January 30, 2022 will ''bolster economy and efficiency in Federal procurement.'' 86 FR 22835. The order builds on the foundation established by Executive Order 13658, ''Establishing a Minimum Wage for Contractors,'' which was signed by President Barack Obama on February 12, 2014. *See* 79 FR 9851. On July 22, 2021, the Department published a NPRM, ''Increasing the Minimum Wage for Federal Contractors,'' RIN 1235–AA41, and invited public comments. *See* 86 FR 38816. The comment period was scheduled to close August 23, 2021. A request was made to extend the comment period. The Department is granting this request in part and extending the comment period to August 27, 2021.

Signed at this 30th day of July, 2021.

Jessica Looman,

Acting Administrator, Wage and Hour Division.

[FR Doc. 2021–16649 Filed 8–3–21; 8:45 am]

BILLING CODE 4510–27–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 950

[SATS No. WY–049–FOR; Docket ID: OSM–2021–0003; S1D1S SS08011000 SX064A000 212S180110; S1D1S SS08011000 SX064A000 21XS501520]

Wyoming Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; opening of public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Wyoming regulatory program (hereinafter, the

Wyoming program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Wyoming proposes revisions to its program, which includes rules regarding the disposal of decommissioned wind turbine blades and towers as backfill, in response to legislative changes made during the 2020 legislative session. In addition, revisions were made to Chapter 2: Permit Application Requirements for Surface Coal Mining Operations, to correct grammatical errors and provide consistency with the Secretary of State's Rules on Rules. The revised rules address several national, state, and local issues associated with wind energy generation, maintenance, and upgrades, as well as the resulting stockpile of decommissioned wind turbine blades and towers.

This document gives the times and locations that the Wyoming program and proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., m.d.t. September 3, 2021. If requested, we may hold a public hearing or meeting on the amendment on August 30, 2021. We will accept requests to speak at a hearing until 4:00 p.m., m.d.t. on August 19, 2021.

ADDRESSES: You may submit comments, identified by SATS No. WY–050–FOR, by any of the following methods:

- *Mail/Hand Delivery:* Mr. Jeffrey Fleischman, Director, Denver Field Division; Office of Surface Mining Reclamation and Enforcement; Casper Area Office; 100 East ''B'' Street, Room 4100, P.O. Box 11018, Casper, Wyoming 82601.
- *Fax:* (307) 261–6552.
- *Federal eRulemaking Portal:* The amendment has been assigned Docket ID: OSM–2021–0003. If you would like to submit comments, go to *http://www.regulations.gov.* Follow the instructions for submitting comments.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than the ones listed above will be included in the docket for this rulemaking and considered.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Wyoming program, this amendment, a listing of any scheduled public hearings or meetings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Casper Area Office or the full text of the program amendment is available for you to read at *http://www.regulations.gov.*

Jeffrey Fleischman, Director Denver Field Division, Office of Surface Mining Reclamation and Enforcement, Dick Cheney Federal Building, 150 East B Street, Room 1018, Casper, Wyoming 82601–1018. Telephone: (307) 261–6550. Email: *jfleischman@osmre.gov.*

In addition, you may review a copy of the amendment during regular business hours at the following location: Kyle Wendtland, Administrator, Land Quality Division, Wyoming Department of Environmental Quality, 200 West 17th Street, Suite 10, Cheyenne, Wyoming 82002. Telephone: 307–777–7046. Email: *Kyle.Wendtland@wyo.gov.*

FOR FURTHER INFORMATION CONTACT: Jeffrey Fleischman, Division Chief, Casper Area Office. Office of Surface Mining Reclamation and Enforcement, Dick Cheney Federal Building, P.O. Box 11018, 150 East B Street Casper, Wyoming 82601–1018. Telephone: (307) 261–6555. Email: *jfleischman@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Wyoming Program
II. Description of the Proposed Amendment
III. Public Comment Procedures
IV. Statutory and Executive Order Reviews

I. Background on the Wyoming Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its approved, State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior approved the Wyoming program on November 26, 1980. You can find background information on the Wyoming program, including the Secretary's findings, the disposition of comments, and conditions of approval in the November 26, 1980, **Federal Register** (45 FR 78637). You can also find later actions concerning Wyoming's program and program amendments at 30 CFR 950.11, 950.12, 950.15, 950.16, and 950.20.

II. Description of the Proposed Amendment

By letter dated June 4, 2021 (Administrative Record No. WY–054–01), Wyoming sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). Wyoming submitted the amendment in response to legislative changes made, through Wyoming House Bill HB0129 during the 2020 legislative session, to Wyoming Statute (W.S.) § 35–11–402(a)(xiii), which outlined rules regarding how decommissioned wind turbine blades and towers could be used as backfill in open surface coal mine pits in order to facilitate disposal. Due to the large volume of decommissioned wind turbine blades and towers, a lack of scalable recycling methods to facilitate their disposal, and the absence of guidance in SMCRA regarding the disposal of non-mining-generated, solid wastes at a coal mine, the Wyoming Legislature provided the Land Quality Division with the authority to develop rules and regulations regarding such disposal. The revised rules address local, state, and national issues associated with the resulting stockpile of decommissioned wind turbine blades and towers, as a result of wind energy generation, upgrades, and routine maintenance.

In addition, revisions were made to Chapter 2: Permit Application Requirements for Surface Coal Mining Operations, to provide consistency with the Wyoming Secretary of State's Rules on Rules, as well as correct grammatical errors. The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES** or at *http://www.regulations.gov.*

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

Electronic or Written Comments

If you submit written or electronic comments on the proposed rule during the 30-day comment period, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended

change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

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 review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., m.d.t. on August 19, 2021. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Statutory and Executive Order Reviews

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993, the approval of State program amendments is exempted from OMB review under Executive Order 12866. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment.

We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 950

Intergovernmental relations, Surface mining, Underground mining.

David Berry,

Regional Director, Western Region.

[FR Doc. 2021–16545 Filed 8–3–21; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2021–0546]

RIN 1625–AA08

Special Local Regulation; Ohio River, Louisville, KY

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a special local regulation on the Ohio River at mile marker 596. This action is necessary to provide for the safety of life on these navigable waters during the Captain's Quarters Sailing Regatta from October 9, 2021 through October 10, 2021. This proposed rulemaking would prohibit persons and vessels from being in the limited access area unless authorized by the Captain of the Port Ohio Valley or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before August 24, 2021.

ADDRESSES: You may submit comments identified by docket number USCG–2021–0546 using the Federal Decision Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Petty Officer Taylor Mudrock, Sector Ohio Valley, U.S. Coast Guard 502–779–5337, *Taylor.A.Mudrock@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

On July 5, 2021, River Cities Community Sailing Program notified the Coast Guard that it will be conducting a sailing regatta from noon through 5 p.m. on October 9, 2021 and October 10, 2021. The regatta will consist of

approximately 35 sailing vessels ranging in size from 22 feet to 35 feet.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters during, the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The COTP is proposing a special local regulation from noon through 5 p.m. on October 9, 2021 and October 10, 2021. This special local regulation will cover all navigable waters from mile markers 594 to 598. The duration of the zone is intended to ensure the safety of the sailing vessels during the regatta. No vessel or person would be permitted to enter the limited access area without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed 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 12866 and 13563 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. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and duration of the special local regulation. This special local regulation would restrict transit on a four-mile stretch of the Ohio River for five hours on two days. Moreover, the Coast Guard would issue Broadcast Notice to Mariners (BNMs), Local Notices to Mariners (LNMs), and Marine Safety Information Bulletins (MSIBs) about this special local regulation so that waterway users may plan according for this restriction on transit, and the rule would allow Bessel to request permission to enter the zone.

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 proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the special local regulation may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed 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 call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would 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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would 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 proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination 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 proposed rule involves a two day sailing competition held annually. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email 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.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2021–0546 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

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

■ 2. Add § 100.T08–0462 to read as follows:

§ 100.T08–0462 Captain's Quarters Sailing Regatta, Louisville, KY. Ohio River MM 594.0 to MM 598.0.

(a) *Regulated area.* The regulations in this section apply to the following area: All waters of the Ohio River from MM 594.0 to MM 598.0, extending the entire width of the river.

(b) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Ohio Valley or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by Sector Ohio Valley command center at 502–779–5422. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

(3) The COTP will provide notice of the regulated area through advanced notice via broadcast notice to mariners and by on-scene designated representatives.

(c) *Enforcement period.* This section will be enforced from noon through 5 p.m. on October 9, 2021 and October 10, 2021.

Dated: July 20, 2021.

A.M. Beach,

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

[FR Doc. 2021–16573 Filed 8–3–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 328

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 120

[EPA–HQ–OW–2021–0328; FRL–6027.4–02–OW]

Notice of Public Meetings Regarding ''Waters of the United States''; Establishment of a Public Docket; Request for Recommendations

AGENCY: Department of the Army, Corps of Engineers, Department of Defense; and Environmental Protection Agency (EPA)

ACTION: Notice; announcement of public meeting dates and solicitation of pre-proposal feedback.

SUMMARY: On June 9, 2021, the U.S. Environmental Protection Agency (EPA) and the Department of the Army announced their intent to revise the definition of ''waters of the United States.'' This process includes two rulemakings: A foundational rule to restore longstanding protections, and a second rulemaking process that builds on that regulatory foundation. The forthcoming foundational rule will propose to restore the regulations defining ''waters of the United States'' that were in place for decades until 2015, with updates to be consistent with relevant Supreme Court decisions. The agencies will also pursue a separate, second rulemaking process that further refines and builds upon that regulatory foundation. The agencies intend to engage with state and tribal co-regulators and the public to inform these two rulemakings. The agencies are committed to learning from the past regulatory approaches—the pre-2015 regulations and guidance, the 2015 Clean Water Rule, and the 2020 Navigable Waters Protection Rule—while engaging with stakeholders and crafting a refined definition of ''waters of the United States.''

This document includes a schedule for initial public meetings to hear from interested stakeholders on their perspectives on defining ''waters of the United States'' under the Clean Water Act and how to implement that definition as the agencies pursue this process. The agencies are also accepting written recommendations from members of the public and are planning further opportunities for engagement. These opportunities will include 10 geographically focused roundtables that will provide for broad, transparent, regionally focused discussions among a full spectrum of stakeholders.

DATES: Written recommendations must be received on or before September 3, 2021. The agencies will hold public meetings on the following dates: August 18, August 23, August 25, August 26, and August 31, 2021. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on these meetings.

ADDRESSES: You may send written feedback, identified by Docket ID No. EPA–HQ–OW–2021–0328, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting written feedback.
- *Email: OW-Docket@epa.gov.* Include Docket ID No. EPA–HQ–OW–

2021–0328 in the subject line of the message.

Instructions: All submissions received must include Docket ID No. EPA–HQ–OW–2021–0328. Written feedback received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit written feedback via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

Damaris Christensen, Oceans, Wetlands and Communities Division, Office of Water (4504–T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564–2281; email address: *WOTUS-outreach@epa.gov,* and Stacey Jensen, Office of the Assistant Secretary of the Army for Civil Works, Department of the Army, 108 Army Pentagon, Washington, DC 20310–0104; telephone number: (703) 459–6026; email address: *usarmy.pentagon.hqda-asa-cw.mbx.asa-cw-reporting@mail.mil.*

SUPPLEMENTARY INFORMATION:

I. Background

''Waters of the United States'' is a threshold term in the Clean Water Act that establishes the geographic scope of federal jurisdiction under the Act. Many Clean Water Act programs, including sections 303 (Water Quality Standards and Total Maximum Daily Loads), 311 (oil spill programs), 401 (water quality certifications), 402 (pollutant discharge permits), and 404 (dredged and fill material discharge permits), address ''navigable waters,'' defined in the statute as ''the waters of the United States, including the territorial seas.'' Since the 1970s, the U.S. Environmental Protection Agency (EPA) and the U.S. Department of the Army (''Army,'' collectively ''the agencies'') have defined ''waters of the United States'' by regulation. The Navigable Waters Protection Rule (NWPR), the agencies' most recent regulation revising the definition of ''waters of the United States,'' was published in the **Federal Register** on April 21, 2020 (85 FR 22250). The NWPR defines categories of waters that are jurisdictional and categories that are not jurisdictional. Eighty-one parties have filed fifteen complaints challenging the NWPR in eleven different district courts.

II. Review of the NWPR

On January 20, 2021, the President signed Executive Order 13990 directing federal agencies to review rules issued in the prior four years that are or might conflict with the policy stated in the order. The order provides that ''[i]t is, therefore, the policy of my Administration to listen to the science; to improve public health and protect our environment; to ensure access to clean air and water; to limit exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; to reduce greenhouse gas emissions; to bolster resilience to the impacts of climate change; to restore and expand our national treasures and monuments; and to prioritize both environmental justice and the creation of the well-paying union jobs necessary to deliver on these goals.'' 86 FR 7037, section 1 (published January 25, 2021, signed January 20, 2021). The order ''directs all executive departments and agencies (agencies) to immediately review and, as appropriate and consistent with applicable law, take action to address the promulgation of Federal regulations and other actions during the last four years that conflict with these important national objectives, and to immediately commence work to confront the climate crisis.'' *Id.* at 7037, section 2(a). ''For any such actions identified by the agencies, the heads of agencies shall, as appropriate and consistent with applicable law, consider suspending, revising, or rescinding the agency actions.'' *Id.* The order also specifically revoked Executive Order 13778 of February 28, 2017 (Restoring the Rule of Law, Federalism, and Economic Growth by Reviewing the ''Waters of the United States'' Rule), which had initiated development of the agencies' two-step process to repeal and replace the 2015 Clean Water Rule, culminating in promulgation of the NWPR.

In conformance with Executive Order 13990, the agencies reviewed the NWPR and have decided to initiate two new rulemakings. The agencies considered the following factors in making this decision, including but not limited to: The text of the Clean Water Act; Congressional intent and the objective of the Clean Water Act; Supreme Court precedent; the current and future harms to the chemical, physical, and biological integrity of the nation's waters due to the NWPR; concerns raised by stakeholders about the NWPR, including implementation-related issues; the principles outlined in the Executive Order; and issues raised in ongoing litigation challenging the NWPR. EPA and the Army have substantial and legitimate concerns that the NWPR did not appropriately consider the effect of the revised definition of ''waters of the United States'' on the integrity of the nation's waters. Notwithstanding these concerns and ongoing litigation, the agencies will continue to implement the NWPR until it is no longer in effect, as a result of either a new final rule going into effect or by virtue of a court order.

III. New Rulemakings

The agencies are initiating two new rulemakings. First, the agencies intend to propose restoring the longstanding Clean Water Act regulations that were in place for decades prior to 2015, as amended to be consistent with relevant Supreme Court decisions.[1] The agencies then intend to propose a second rule that builds on that regulatory foundation. During the development of both rules, the agencies will listen to and engage with states, tribes, and interested stakeholders about their experiences implementing the NWPR, the 2015 Clean Water Rule, and the pre-2015 regulatory regime. The agencies' rulemaking process will be guided by the following considerations:

- Ensure the rule will further the principal objective of the Act as set forth by Congress, which is to ''restore the chemical, physical, and biological integrity of the Nation's waters.'' 33 U.S.C. 1251.
- Consider the latest peer-reviewed and relevant science.

[1] In *United States* v. *Riverside Bayview Homes,* 474 U.S. 121 (1985), in a unanimous opinion, the Supreme Court deferred to the Corps' judgment and upheld the inclusion of adjacent wetlands in the regulatory definition of ''waters of the United States.'' In *Solid Waste Agency of Northern Cook County* v. *U.S. Army Corps of Engineers,* 531 U.S. 159 (2001), the Court (in a 5–4 opinion) held that the use of ''isolated'' non-navigable intrastate ponds by migratory birds was not by itself a sufficient basis for the exercise of Federal regulatory authority under the CWA. In *Rapanos* v. *United States,* 547 U.S. 715 (2006), a four-Justice plurality interpreted ''waters of the United States'' as covering ''relatively permanent'' waters as well as wetlands with a ''continuous surface connection'' to such water bodies. Justice Kennedy's concurring opinion concluded that a water or wetland must possess a ''significant nexus'' to traditional navigable waters to be a ''water of the United States.''

• Prioritize practical implementation approaches for state and tribal co-regulators.

• Reflect the experiences of, and input received from, landowners, the agricultural community, states, tribes, local governments, community organizations, environmental groups, and disadvantaged communities with environmental justice concerns.

IV. Stakeholder Engagement

To assist the agencies in the rulemaking process, the agencies welcome feedback that can be provided through the open public docket or through participation at one of several public meetings. This feedback will inform the rulemaking process; however, the agencies will not be responding to individual recommendations. Issues that the agencies are particularly interested in getting feedback on include:

• *Implementation.* The agencies seek input on co-regulator and stakeholder experiences with implementing the various regulatory regimes. In particular, the agencies would like feedback on significant nexus analyses under the pre-2015 regulatory regime and the 2015 Clean Water Rule, as well as the typical year analysis under the NWPR. Are there implementation successes and challenges in assessing specific types of sites? If there are challenges, what types of implementation assistance would be helpful? Are there ways in which these assessments could be more efficient? Are there tools that have been, or could be, developed to assist in determining jurisdiction?

• *Regional, State, and Tribal interests.* The agencies request feedback on how or whether states and tribes have taken any actions in response to changes in the jurisdictional scope of ''waters of the United States'' under the NWPR. In addition, the agencies request recommendations regarding whether there are certain waters that could be addressed by regionalized approaches. The agencies are committed to listening to specific tribal interests that should be considered in any revised definition. The agencies are also seeking input on the use and value of the jurisdictional category for interstate waters.

• *Science.* Consistent with Executive Order 13990, the agencies request identification of relevant science related to how streams, wetlands, lakes, and ponds restore and maintain the chemical, physical, and biological integrity of the nation's waters, including relevant literature that has been published since EPA's 2015 Report *Connectivity of Streams and Wetlands to Downstream Waters: A Review and Synthesis of the Scientific Evidence.*

• *Environmental justice interests.* Consistent with Executive Order 13990, the agencies request feedback on how to better engage to ensure input is received from communities with environmental justice interests. How does the jurisdictional status of waters affect communities that are overburdened with environmental pollution? How is the implementation of NWPR impacting low-income communities, and other disadvantaged communities? Can the jurisdictional status of waters be linked to environmental justice concerns, and, if so, what is the basis?

• *Climate implications.* Consistent with Executive Order 13990, the agencies request feedback on how climate change affects the chemical, physical, and biological integrity of the nation's waters. How should the agencies account for the effects of a changing climate in identifying jurisdictional waters? Are there particular types of waters that are especially important in protecting the nation's waters in the face of a changing climate, and, if so, what scientific evidence supports these conclusions?

• *The scope of jurisdictional tributaries.* Multiple rules, judicial decisions, and longstanding practice protected ephemeral, intermittent, and perennial streams that met applicable criteria for jurisdiction as tributaries that are ''waters of the United States.'' Ephemeral streams were then categorically excluded from jurisdiction in the NWPR, and some intermittent streams and even some perennial streams are no longer jurisdictional under the NWPR. The agencies seek feedback on whether certain characteristics, such as indicators of channelization; physical indicators such as indicators of ordinary high water mark; flow regime; flow duration; watershed size; landscape position; stream network density; or distance from a traditional navigable water, territorial sea, or interstate water should inform determinations about which tributaries could be considered jurisdictional as a class, and which decisions are best left to individual, case-specific significant nexus determinations similar to the agencies' practice from 2007 through 2015. The agencies are particularly interested in feedback regarding how to identify ephemeral streams that should be jurisdictional as tributaries, as they are the dominant stream type in the arid West and in many headwater regions. The agencies are interested in understanding the impacts of their exclusion from the regulations under the Clean Water Act by the NWPR.

• *The scope of jurisdictional ditches.* Historically, the agencies have recognized that ditches that reroute otherwise jurisdictional tributaries are themselves jurisdictional as tributaries. In addition, in practice, many other ditches have been considered generally *not* jurisdictional. The 2015 Clean Water Rule and later the NWPR, for the first time, excluded many ditches explicitly in rule language. The agencies solicit feedback on whether flow regime, physical features, excavation in aquatic resources versus uplands, type or use of the ditch (*e.g.,* irrigation and drainage), biological indicators like presence of fish, or other characteristics could provide clear and implementable distinctions between jurisdictional and non-jurisdictional ditches.

• *The scope of adjacency.* Each regulatory definition of ''waters of the United States'' has taken a different approach to determining adjacency for purposes of jurisdiction under the Act and to the jurisdiction of non-adjacent waters:

a. Wetlands that may have been considered adjacent under some but not all definitions of ''waters of the United States'' include wetlands behind artificial berms, which were considered adjacent under the pre-2015 regulatory regime and the 2015 Clean Water Rule regardless of the presence or absence of a hydrologic surface connection, but required a surface water connection under the NWPR. The pre-2015 regulatory regime and the 2015 Clean Water Rule also included ''neighboring'' wetlands within the definition of ''adjacent,'' while the NWPR generally did not.

b. Adjacent lakes and ponds that were not jurisdictional as tributaries were covered under the other waters category in the pre-2015 regulations if they met certain criteria. Adjacent lakes and ponds were included with adjacent wetlands in an adjacent waters category in the 2015 Clean Water Rule. Lakes and ponds with certain surface water connections are jurisdictional under the NWPR.

c. Another category of waters includes non-adjacent, intrastate, non-navigable waters, such as certain prairie potholes, playa lakes, Carolina Bays, and more, that are not proximate (reasonably close) to jurisdictional waters or lack natural tributary connections or ditching to connect them to a tributary network. These waters are typically non-jurisdictional under the NWPR and, as a matter of practice, following Supreme Court decisions the agencies did not assert jurisdiction over them under the

pre-2015 regulatory regime. These waters would have been jurisdictional under the 2015 Clean Water Rule where they met specific criteria and were found to have a significant nexus to downstream traditional navigable waters, interstate waters, or territorial seas.

The agencies are interested in identifying characteristics that could allow for clarity, implementability, and/or regionalization in defining adjacency and identifying jurisdictional waters, including whether there are appropriate distances or other factors to limit adjacency, whether there are certain situations where case-specific significant nexus determinations would more appropriately determine jurisdiction, and whether there are certain types of waters with particular features or characteristics that could provide clear and implementable distinctions between jurisdictional and non-jurisdictional waters. The agencies are also interested in recommendations for implementation approaches to address any of these types of waters.

• *Exclusions from the definition.* The agencies request feedback on the implementability and clarity of exclusions present in the NWPR and identified in the 2015 Clean Water Rule or the pre-2015 regulations and the preambles to those regulations. Was the scope of these exclusions appropriate under the Clean Water Act, easy to understand, and implementable? Are the NWPR definitions of prior converted cropland and waste treatment systems appropriate under the Clean Water Act, easy to understand, and implementable? Did the exclusions have any benefits or harmful impacts? Are there regional differences with these features and/or systems that should be considered?

V. Public Meetings and Outreach

The agencies will hold a series of public meetings intended to solicit recommendations as the agencies pursue the development of both rules. During these meetings, the agencies intend to provide brief background information on the rulemaking process and stakeholders will have the opportunity to provide input, particularly with regard to the directives in Executive Order 13990 and the topics above. The agencies will hold four meetings open to all stakeholders and an additional session for small entities, and reserve a time for an additional meeting that will be added in case all speaking slots are filled in earlier meetings.

The public meetings will be held as web conferences in August 2021, with one date reserved in September, if needed. Registration instructions can be found at the following website: *https://www.epa.gov/wotus/public-outreach-and-stakeholder-engagement-activities.* Persons or organizations wishing to provide verbal recommendations during the meetings will be selected on a first-come, first-serve basis. Due to the expected number of participants, individuals will be asked to limit their spoken presentation to three minutes. Once the speaking slots are filled, participants may be placed on a standby list to speak or continue to register to listen to the recommendations. The meetings will be recorded and posted on EPA's website. Supporting materials and written feedback from those who do not have an opportunity to speak can be submitted to the docket as described above. The schedule for the ''waters of the United States'' meetings is as follows:

—August 18, 2021, from 3 p.m. to 5 p.m. Eastern,
—August 23, 2021, from 1 p.m. to 3 p.m. Eastern,
—August 25, 2021, from 3 p.m. to 5 p.m. Eastern,
—August 26, 2021, from 6 p.m. to 8 p.m. Eastern, and
—August 31, 2021, from 3 p.m. to 5 p.m. Eastern.

The agencies have also reserved September 2, 2021, from 2 p.m. to 4 p.m. Eastern, for an additional meeting that will be added in case all speaking slots are filled in earlier meetings.

In addition, the agencies are initiating Federalism and tribal consultations for the proposed rulemaking to restore the regulations defining ''waters of the United States'' in place from 1986 until 2015, amended to be consistent with relevant Supreme Court decisions. The agencies also intend to host a series of dialogues with state and tribal coregulators this fall to discuss both rulemakings.

Finally, the rulemaking efforts of the past decade have highlighted the regional variability of water resources and the importance of close engagement with stakeholders to understand the specifics of how they experience regulation under varying definitions of waters of the United States. As an agency, we will honor our commitment to listen and learn from diverse perspectives by hosting 10 roundtables representing different regions of the country and encouraging broad participation that reflects diverse views. These 10 regional roundtables will allow a full spectrum of stakeholders to provide their perspectives about what has worked and what has not worked within their geographic areas in previous regulatory efforts with each other and in the presence of EPA and Army leadership. These roundtables will highlight similarities and differences across geographic regions, while emphasizing particular water resources that are characteristic of or unique to each region, and providing site-specific feedback about implementation. Information on the roundtables will be posted on the EPA website above.

Vance F. Stewart III,

Acting Principal Deputy, Office of the Assistant Secretary of the Army for Civil Works, Department of the Army.

John Goodin,

Director, Office of Wetlands, Oceans and Watersheds, Environmental Protection Agency.

[FR Doc. 2021–16643 Filed 8–3–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2020–0445; FRL–8779–01–R4]

Air Plan Approval; SC; Revisions to Definitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of South Carolina, through the South Carolina Department of Health and Environmental Control (SC DHEC or Department), on April 24, 2020. The SIP revision updates the definition of ''Spec. Oil (Specification Oil)'' and makes minor updates to formatting and numbering. EPA is proposing to approve this revision pursuant to the Clean Air Act (CAA or Act) and implementing federal regulations.

DATES: Comments must be received on or before September 3, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2020–0445 at *www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* 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 a discussion of all points you wish to make. 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 *www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Tiereny Bell, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9088. Ms. Bell can also be reached via electronic mail at *bell.tiereny@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What is EPA proposing?

On April 24, 2020, SC DHEC submitted a SIP revision to EPA for approval that includes changes to South Carolina Regulation 61–62.1, Section I—*Definitions,* including a revised definition of ''Spec. Oil (Specification Oil)'' and updates to numbering and formatting within this regulation.[1] EPA is proposing to approve these changes pursuant to the CAA.

II. Background

SC DHEC has requested incorporation of several changes to South Carolina Regulation 61–62.1, Section I—*Definitions* into South Carolina's SIP. First, SC DHEC's SIP revision proposes minor updates to numbering and formatting within South Carolina Regulation 61–62.1, Section I—*Definitions.*

Second, SC DHEC proposes to revise the definition of ''Spec. Oil (Specification Oil)'' at Paragraph 97(a) within the definition of ''Used Oil.'' Specifically, the revised definition of ''Spec. Oil'' would remove the phrase ''Nickel—120 ppm [parts per million] maximum,'' thus eliminating the nickel specification for ''Spec. Oil.'' In the South Carolina SIP's definition of ''Used Oil,'' ''Spec. Oil'' and ''Non-Spec. Oil''[2] are listed as ''[t]wo (2) types'' of ''used oil.'' Notably, the terms ''Spec. Oil'' and ''Specification Oil'' do not currently appear anywhere else in South Carolina's SIP outside of the definition of ''Used Oil.''

SC DHEC has indicated that the purpose of its requested change to the definition of ''Spec. Oil'' in South Carolina Regulation 61–62.1, Section I—*Definitions* is to maintain a consistent definition of spec. oil across South Carolina's various regulatory programs. Specifications for spec. oil are also contained in 40 CFR 279.11 and in South Carolina Rule 61–107–.279.11, both of which implement the used oil provisions of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 *et seq.* Neither 40 CFR 279.11 nor South Carolina Rule 61–107–.279.11 include a specification for nickel in those regulations' respective used oil specifications and, therefore, South Carolina's proposed SIP revision would make the definition of ''Spec. Oil'' in South Carolina Regulation 61–62.1, Section I—*Definitions* consistent with the used oil specifications in these other regulations.

III. Analysis of State's Submittal

As mentioned above, the April 24, 2020, SIP revision includes a change to the definition of ''Spec. Oil (Specification Oil)'' within the definition of ''Used Oil'' in South Carolina Regulation 61–62.1, Section I—*Definitions.* Because this change would remove the specification for nickel in ''Spec. Oil,'' it would allow unlimited nickel content in ''Spec. Oil.''

Under section 110(l) of the CAA, EPA cannot approve a SIP revision ''if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 7501 of this title), or any other applicable requirement of this chapter.'' EPA finds that SC DHEC's proposed updated definition of ''Spec. Oil,'' which removes the specification for nickel in ''Spec. Oil,'' is approvable under section 110(l) for two reasons. First, this proposed revision will not interfere with the NAAQS or any other CAA requirement because the revision has no practical effect. ''Spec. Oil'' does not appear anywhere in South Carolina's SIP other than in the definition of ''Used Oil'' itself; the definition of ''Used Oil'' describes ''Spec. Oil'' as just one of ''[t]wo (2) types'' of ''used oil''; and oil that would not meet the definition of ''Spec. Oil'' in the current SIP-approved version of the rule due solely to nickel concentrations above 120 ppm would be still be considered ''Used Oil'' under the regulation.[3] Thus, although the term ''Used Oil'' appears elsewhere in South Carolina's SIP (such as in the definitions of Waste and Municipal Solid Waste), changing the definition of ''Spec. Oil'' will have no practical effect, and therefore, satisfies section 110(l).[4]

Second, SC DHEC's proposed removal of the nickel specification from the definition of ''Spec. Oil'' is not inconsistent with CAA section 129 (relating to solid waste combustion) and is consistent with interrelated solid waste rules codified at 40 CFR parts 241 and 279.[5] The referenced solid waste rules generally relate to the status of used oil when used oil is burned for energy recovery. More specifically, under 40 CFR 241.2, ''used oil which meets the specifications outlined in 40 CFR 279.11'' are ''[t]raditional fuels'' and are therefore not solid waste subject to the requirements of CAA section 129. *See generally* 76 FR 15456, 15502–06 (March 21, 2011). South Carolina's revised definition of ''Spec. Oil'' is consistent with these solid waste rules and, specifically, is consistent with the specifications for used oil in 40 CFR 279.11, which does not include a nickel specification. Thus, South Carolina's proposed rule will not interfere with section 129 of the CAA or any plan promulgated under section 129 of the CAA.

IV. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference South Carolina's Regulation 61–62.1, *Definitions and General Requirements,* Section I—*Definitions,* state effective on April 24, 2020. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the ''For Further

[1] On April 24, 2020, SC DHEC also submitted to EPA SIP revisions to Regulations 61–62.1, Section II—*Permit Requirements*; 61–62.1, Section III—*Emission Inventory and Emissions Statement*; 61–62.1, Section IV—*Source Tests*; 61–62.1, Section V—*Credible Emissions*; 61–62.5, Standard No. 2—*Ambient Air Quality Standards*; 61–62.5, Standard 5.2—*Control of Oxides of Nitrogen (NO_X)*; 61–62.5, Standard 7—*Prevention of Significant Deterioration*; and 61–62.5, Standard 7.1—*Nonattainment New Source Review (NSR).* EPA will address these SIP revisions in separate actions.

[2] ''Non-Spec. Oil (Off Spec Oil)'' is defined as ''[u]sed oil that does not meet the specification above.'' S.C. Code Regs. 61–62.1 § I (97)(b). Therefore, used oil that does not meet the definition of ''Spec. Oil'' is still considered ''Used Oil.'' *Id.*

[3] *See* footnote 2.

[4] Additionally, South Carolina is currently attaining the NAAQS for all criteria pollutants.

[5] These rules are interrelated because CAA Section 129 specifically references the ''Solid Waste Disposal Act [42 U.S.C. 6901 *et seq.*],'' including the definition of ''solid waste'' promulgated pursuant to that act. *See* CAA § 129(g)(6).

Information Contact'' section of this preamble for more information).

V. Proposed Action

EPA is proposing to approve and incorporate into South Carolina's SIP the aforementioned changes to South Carolina Regulation 61–62.1, Section I—*Definitions,* state effective on April 24, 2020. EPA has determined that these revisions meet the applicable requirements of Section 110 of the CAA and the applicable regulatory requirements at 40 CFR part 51.

VI. Statutory and Executive Order Reviews

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

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

In addition, this proposed rule for South Carolina does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because it does not have substantial direct effects on an Indian Tribe. The Catawba Indian Nation Reservation is located within the state of South Carolina. Pursuant to the Catawba Indian Claims Settlement Act, S.C. Code Ann. 27–16–120, ''all state and local environmental laws and regulations apply to the [Catawba Indian Nation] and Reservation and are fully enforceable by all relevant state and local agencies and authorities.'' EPA notes this action will not impose substantial direct costs on Tribal governments or preempt Tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: July 22, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

[FR Doc. 2021–16032 Filed 8–3–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–21–921; RM–11891; DA 21–921; FR ID 41251]

Television Broadcasting Services Henderson, Nevada

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by KVVU Broadcasting Corporation (Petitioner), the licensee of KVVU (FOX), channel 9, Henderson, Nevada. The Petitioner requests the substitution of channel 24 for channel 9 in the DTV Table of Allotments.

DATES: Comments must be filed on or before September 3, 2021 and reply comments on or before September 20, 2021.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Petitioner as follows: Christina Burrow, Esq., Cooley LLP, 1299 Pennsylvania Avenue NW, Suite 700, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647; or Joyce Bernstein, Media Bureau, at *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: In support of its channel substitution request, the Petitioner states that the Commission has recognized that VHF channels have certain characteristics that pose challenges for their use in providing digital television service, including propagation characteristics that allow undesired signals and noise to be receivable at relatively far distances and nearby electrical devices to cause interference. According to the Petitioner, it has received numerous complaints of poor or no reception from viewers, and explains the importance of a strong over-the-air signal in the Las Vegas area during emergencies, when, it states, cable and satellite service may go out of operation. It also explained that improving KVVU's signal would serve the public interest because more than 25 percent of viewers in the Las Vegas area receive television broadcast signals over-the-air. Finally, the Petitioner recognized that the channel 24 noise limited contour would not fully encompass the existing channel 9 contour, but stated that only 152 persons in the lost coverage area would lose service from KVVU–TV, a number the Commission considers *de minimis,* and no viewers would lose access to their first or second over-the-air television service. The Petitioner also performed an analysis using the Commission's *TVStudy* software, which indicated that Petitioner's proposal would result in no more than 0.5 percent new interference to any surrounding co-channel or adjacent-channel facility.

This is a synopsis of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 21–921; RM–11891; DA 21–921, adopted July 27, 2021, and released July 28, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* or call the Consumer & Government Affairs

Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a Notice of Proposed Rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in Section 1.1204(a) of the Commission's rules, 47 CFR 1.1204(a).

See Sections 1.415 and 1.420 of the Commission's rules for information regarding the proper filing procedures for comments, 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICE

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

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

§ 73.622 [Amended]

■ 2. In § 73.622 in paragraph (i), amend the Post-Transition Table of DTV Allotments under Nevada by revising the entry for Henderson to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(i) * * *

Community	Channel No.
* * * * *	
NEVADA	
* * * * *	
Henderson	24
* * * * *	

[FR Doc. 2021–16589 Filed 8–3–21; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–HQ–ES–2021–0043; FF09E21000 FXES11180900000 212]

RIN 1018–BF35

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for Emperor Penguin

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list the emperor penguin (*Aptenodytes forsteri*), a flightless bird species from Antarctica, as a threatened species under the Endangered Species Act of 1973, as amended (Act). This proposal also serves as our 12-month finding on a petition to list the emperor penguin. After a review of the best available scientific and commercial information, we find that listing the species is warranted. Accordingly, we propose to list the emperor penguin as a threatened species with a rule issued under section 4(d) of the Act (''4(d) rule''). If we finalize this rule as proposed, it would add this species to the List of Endangered and Threatened Wildlife and extend the Act's protections to the species.

DATES: We will accept comments received or postmarked on or before October 4, 2021. 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 a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by September 20, 2021.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–HQ–ES–2021–0043, 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, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–HQ–ES–2021–0043, U.S. Fish and Wildlife Service, MS: PRB/3W, 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 Information Requested, below, for more information).

Availability of supporting materials: Supporting documentation used to prepare this proposed rule, including the species status assessment (SSA) report, is available on the internet at *http://www.regulations.gov* under Docket No. FWS–HQ–ES–2021–0043.

FOR FURTHER INFORMATION CONTACT: Elizabeth Maclin, Chief, Branch of Delisting and Foreign Species, Ecological Services Program, U.S. Fish and Wildlife Service, MS: ES, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (telephone 703–358–2171). Persons who use a telecommunications device for the deaf may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, if we determine that a species is an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register**. We will make a determination on our proposal within 1 year, unless we determine that there is substantial disagreement regarding the sufficiency and accuracy of the available data relevant to the proposed listing, in which case we may extend the final determination for not more than 6 months. Listing a species as an endangered or threatened species can only be completed by issuing a rule.

What this document does. We propose to list the emperor penguin as a threatened species with a 4(d) rule under the Act.

The basis for our action. Under the Act, we may determine that a species is

an endangered or threatened species because of any of five factors: (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 determined that the emperor penguin is likely to become endangered within the foreseeable future throughout a significant portion of its range, meeting the Act's definition of a threatened species. The emperor penguin is a sea-ice-obligate seabird distributed around the entire coastline of Antarctica. The global population is estimated at 270,000–280,000 breeding pairs. Given the influence that weather and climate have in affecting the extent and duration of sea ice and relatedly prey abundance around Antarctica, the effects of climate change present the most substantial threat facing the species.

We are also proposing a section 4(d) rule. When we list a species as threatened, section 4(d) of the Act (16 U.S.C. 1533(d)) allows us to issue regulations that are necessary and advisable to provide for the conservation of the species. Accordingly, we are proposing a 4(d) rule for the emperor penguin that would prohibit import, export, take, possession and other acts with unlawfully taken specimens, interstate or foreign commerce in the course of a commercial activity, or sale or offer for sale. It would also be unlawful to attempt to commit, to solicit another to commit, or to cause to be committed any such conduct. The proposed 4(d) rule would provide exceptions for certain activities with emperor penguins that are permitted under the Antarctic Conservation Act of 1978, as amended (16 U.S.C. 2401 *et seq.*) and its implementing regulations in title 45 of the Code of Federal Regulations (CFR) at part 670. An exception is also proposed for interstate commerce from public institutions to other public institutions, specifically museums, zoological parks, and scientific or educational institutions that meet the definition of ''public'' at 50 CFR 10.12. We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances, such as for scientific purposes, or the enhancement of propagation or survival of the species in the wild.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other governmental agencies, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) The species' biology, range, and population trends, including:

(a) Population trends at breeding colonies;

(b) Genetics and taxonomy, particularly related to the four known metapopulations and the areas of Antarctica that have not yet been analyzed;

(c) Historical and current range, including redistribution patterns in relation to catastrophic events;

(d) Colony names and locations;

(e) Sea-ice conditions in Antarctica, and projected trends;

(f) Modeling efforts of sea-ice conditions using the Community Earth System Model Large Ensemble project and/or other models to simulate sea ice in Antarctica as it relates to emperor penguins; and

(g) Past and ongoing conservation measures for the species, its habitat, or both.

(2) Factors that may affect the continued existence of the species, which may include destruction, modification, or curtailment of habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; the inadequacy of existing regulatory mechanisms; or other natural or manmade factors.

(3) Biological, commercial trade, and relevant data concerning any threats (or lack thereof) to this species and existing regulations that may be addressing those threats.

(4) Information on regulations that are necessary and advisable to provide for the conservation of the emperor penguin and that the Service can consider in developing a 4(d) rule for the species. In particular, we seek information concerning the extent to which we should include the Act's section 9 prohibitions (16 U.S.C. 1538) in the 4(d) rule, or whether we should consider including any other prohibitions or exceptions in the 4(d) rule.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

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**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov.*

Because we will consider all substantive comments and information we receive during the comment period, our final determination may differ from this proposal. Based on the best available scientific and commercial information, we may conclude that the species is endangered instead of threatened, that the species is threatened throughout its range instead of in a significant portion of its range, or that the species does not warrant listing as either an endangered species or a threatened species. We may change the parameters of the prohibitions or the exceptions to those prohibitions in the 4(d) rule if we conclude it is appropriate in light of comments and new information we receive. For example, we may expand the prohibitions to include prohibiting additional activities if we conclude that those additional activities are not compatible with conservation of the species. Conversely, we may establish additional exceptions to the prohibitions in the final rule if we conclude that the activities would facilitate or are compatible with the conservation and recovery of the species.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** at least 15 days before the hearing. For the immediate future, we will provide these public hearings using webinars that will be announced on the Service's website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On December 5, 2011, we received a petition from the Center for Biological Diversity to list the emperor penguin as endangered or threatened under the Act. On January 22, 2014, we published a 90-day finding that the petition presented substantial scientific and commercial information indicating that the petitioned action may be warranted; that document also initiated a status review for the emperor penguin (79 FR 3559).

Supporting Documents

We prepared a species status assessment (SSA) for the emperor penguin, in consultation with species experts (Service 2021, entire). The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species. 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 appropriate specialists regarding the SSA. The Service received six responses. We worked with scientists that have expertise with the species and its habitat, modeling sea ice in Antarctica, and projecting the response of emperor penguins under various climate change emissions scenarios.

I. Proposed Listing Determination

Background

A thorough review of the taxonomy, life history, and ecology of the emperor penguin is presented in the SSA report (Service 2021; available at *http://www.regulations.gov* under Docket No. FWS–HQ–ES–2021–0043).

Taxonomy

The emperor penguin (*Aptenodytes forsteri*) is a recognized species (ITIS 2020, unpaginated). In 1844, the head of the ornithology section of the British Museum in London (George Robert Gray) separated emperor penguins from king penguins (*A. patagonicus*), their closest relatives (Wienecke et al. 2013, p. 24; ITIS 2020, unpaginated).

The emperor penguin appeared to be panmictic—genetically homogeneous at the continent scale—which implies the entire species shares a common demographic history (Cristofari et al. 2016, p. 2). However, the most recent studies on the genetic differentiation of emperor penguins revealed at least four metapopulations (*i.e.,* regional groups of connected populations of a species), with some degree of connectivity among the metapopulations, and very high connectivity between breeding colonies within each metapopulation (Younger et al. 2017, p. 3888). However, our understanding of gene flow for emperor penguins is incomplete, as not all colonies have been included in genetic analyses. For example, no colonies from West Antarctica have been sampled.

Physical Description

Penguins are flightless birds that are highly adapted for the marine environment. They are excellent swimmers and can dive to great depths (Australian Antarctic Division 2020, unpaginated). The emperor penguin is the tallest and heaviest of all living penguin species (Australian Antarctic Division 2020, unpaginated). Adults may weigh up to 40 kilograms (88 pounds) and are as tall as 114 centimeters (45 inches) (National Geographic 2020, unpaginated). Males and females are similar in plumage and size, although males are slightly larger than females. Emperor penguins have large reserves of energy-giving body fat, excellent insulation in the form of several layers of very dense scale-like feathers, and strong claws for gripping the ice (Australian Antarctic Division 2020, unpaginated).

Range and Distribution

The emperor penguin is endemic to Antarctica and has a pan-Antarctic distribution, meaning the species occurs around the entire continental coastline of Antarctica (see figure 1, below, for distribution of breeding colony locations). The species breeds mainly on fast ice, which is sea ice attached or ''fastened'' to the coast, between 66 °S and 78 °S latitude along the coast of Antarctica (Williams 1995, p. 153; Fretwell and Trathan 2020, p. 7). No gaps larger than 500 kilometers (311 miles) occur between colonies, except in front of large ice shelves that are probably unsuitable habitats because of the disturbance of iceberg calving (Fretwell and Trathan 2020, p. 10).

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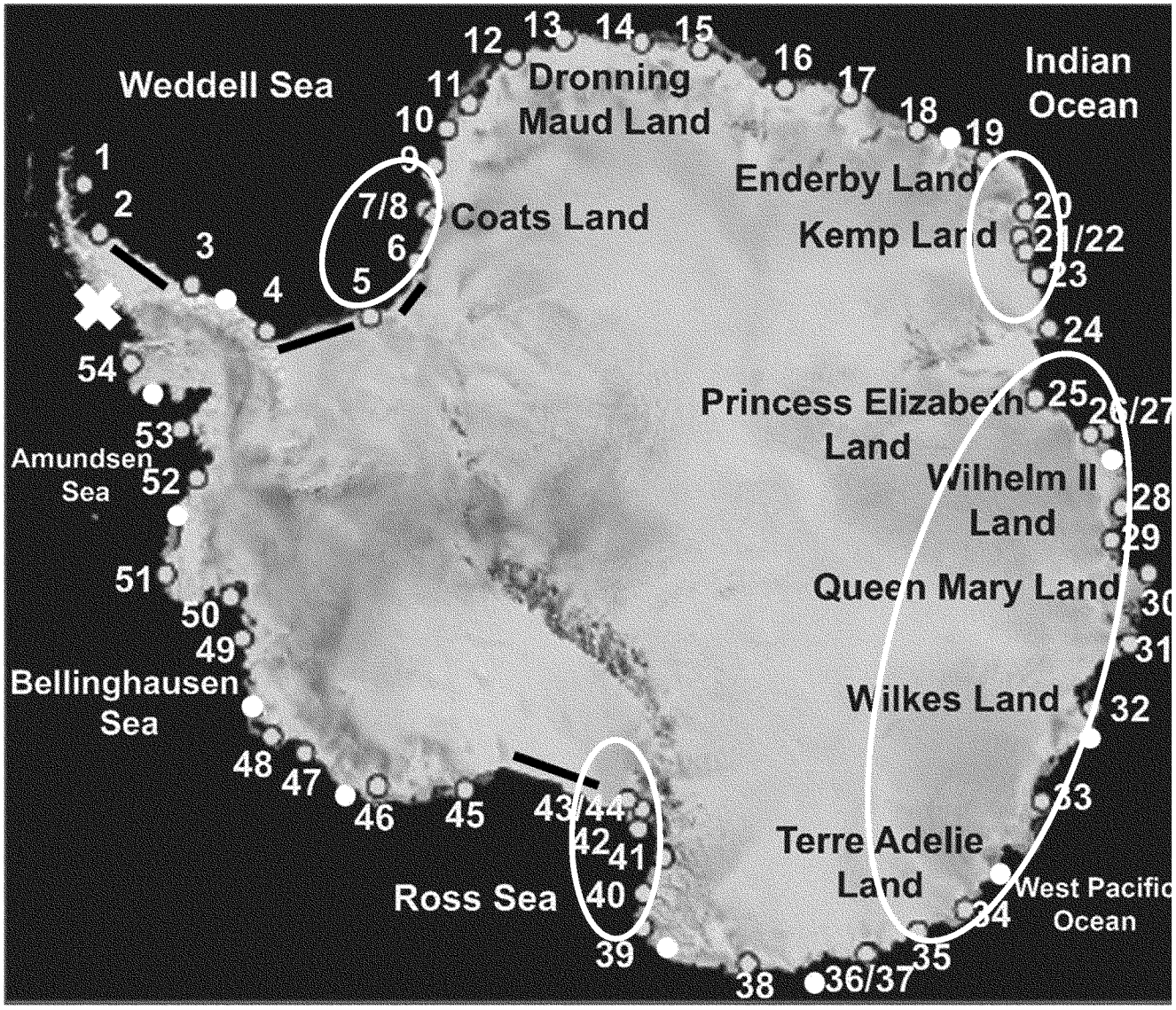

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Figure 1. Distribution of known emperor penguin breeding colonies as of 2020 (numbered dots), including four colonies that were not extant in 2019 (7, 15, 18, 37) and the extirpated Dion Islets colony with approximate location on the peninsula (marked as X). The unnumbered white dots with approximate locations are 11 colonies that were discovered or rediscovered in 2019. Black lines are the fronts of large ice shelves and probably unsuitable habitat. Four white polygons approximately represent the four known metapopulations (Credit for data and figure: Fretwell and Trathan 2009; Fretwell et al. 2012, 2014; Fretwell and Trathan 2020; Wienecke 2011; Ancel et al. 2014; LaRue et al. 2015; Younger et al. 2017; Jenouvrier et al. 2020; also see figures 2.1 and 2.10 in Service 2021).

Life History

The emperor penguin has a long breeding cycle, approximately 8 to 9 months, commencing in the austral (southern) fall to complete the rearing of a single chick per pair within a year. It is the only warm-blooded Antarctic species that breeds during the austral winter and is uniquely adapted for doing so (Trathan et al. 2020, p. 3). The breeding cycle for the species is similar throughout its range, although the timing may vary slightly between colonies depending on the regional sea ice conditions, with some starting sooner and others later (Williams 1995, p. 20; Wienecke et al. 2013, in Trathan et al. 2020, p. 3). The Pointe Géologie colony in Terre Adélie, East Antarctica (colony #35 in figure 1, above) has been monitored annually for more than six decades. Most of our understanding of emperor penguin behavior patterns at breeding colonies is based on what has been learned from this site. Behavior patterns at this colony during the breeding season are well known, but much of the species' ecology at sea is poorly known. In the wild, the average life span is estimated up to 15 to 20 years (National Geographic 2020, unpaginated), although demographic models indicated the average life span is 10–12 years (Jenouvrier 2021, pers. comm). One generation is estimated at 16 years (Jenouvrier et al. 2014, p. 717). Age at first breeding is 5 years old (Mougin and Beveren 1979, in Williams 1995, p. 160; Jenouvrier et al. 2005, Appendix A).

Population Biology

Arrival at breeding colonies is synchronous with when annual sea ice begins to form in March/April. Emperor penguins are serially monogamous, but mate fidelity is low between breeding

seasons (Williams 1995, p. 160). Females lay one egg. Males incubate the egg on their feet while females go to sea to forage. Once the egg hatches, males and females alternate between chick-rearing duties and foraging until the chick can thermoregulate independently, and then both adults forage simultaneously to provide enough food for their growing chick. It takes about 150 days from hatching to fledging before chicks depart from the colony (Stonehouse 1953, p. 28). Juveniles come back to a colony at approximately 4 years of age and breed for the first time at about 5 years of age (Jenouvrier et al. 2005, Appendix A). Yearlings and subadults can regularly occur at colonies, but they do not yet breed (Wienecke 2021, pers. comm.).

Breeding success varies from year to year in relation to both biotic factors (mainly food availability) and abiotic factors (*e.g.,* ice conditions, heavy precipitation). In general, breeding success for *Aptenodytes* species is 0.6–0.8 chicks per pair while laying only a single-egg clutch (Williams 1995, p. 33). At the Point Géologie colony, breeding success for emperor penguin varied over six decades from 2 to 88 percent (Jenouvrier et al. 2005, entire; Jenouvrier et al. 2009, entire). In the same season, breeding success may vary among colonies (Robertson et al. 2014, p. 257). Approximately 80 percent of mature emperor penguins breed every year (Jenouvrier et al. 2005, p. 2900). The mean survival rate is estimated to be 95 percent for adults, and 40 percent for juveniles (Abadi et al. 2017, p. 1357; Mougin and Beveren 1979, in Williams 1995, p. 160). At Point Géologie, annual adult survival was 60–98 percent over six decades (Barbraud and Weimerskirch 2001, in Jenouvrier et al. 2012 appendices, p. 31). The population growth rate of long-lived species is mainly sensitive to changes in adult survival (Barbraud and Weimerskirch 2001, p. 184).

Population Size

As of 2020, 61 known emperor penguin breeding colonies are extant around Antarctica (Fretwell and Trathan 2020; Fretwell and Trathan 2009; Fretwell et al. 2012, 2014; Wienecke 2011; Ancel et al. 2014; LaRue et al. 2015). The global population size is estimated at approximately 270,000–280,000 breeding pairs or 625,000–650,000 individual birds (Trathan et al. 2020, p. 4; National Geographic 2020, unpaginated; Fretwell and Trathan 2020, p. 10). Sea ice surrounding Antarctica is described within five sectors (Weddell Sea, Indian Ocean, Western Pacific Ocean, Ross Sea, and Bellingshausen Sea-Amundsen Sea; see figure 2, below), which may approximately correspond to the known genetic variation among colonies and the Southern Ocean as a whole. The Ross Sea and Weddell Sea sectors contain the highest abundance of emperor penguins relative to the other three sectors.

Data sources include ground and aerial surveys, particularly satellite imagery. Most of the colonies have never been, and perhaps never will be, visited by humans because most breeding colonies are not practical to visit. They are too remote from occupied research stations, and the emperor penguin breeding season occurs during the austral winter, when ground visits to breeding colonies are not feasible with existing techniques (Jenouvrier et al. 2014a, p. 715; Ancel et al. 2014, p. 1). Satellite imaging makes it possible to monitor inaccessible colony locations and estimate colony sizes; although such estimates of colony sizes may be imprecise because colonies move with the wind (Trathan 2021, pers. comm.), they provide the best available information for inaccessible colonies.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an endangered species or a threatened species. The Act defines an endangered species as a species that is ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as a species that is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The Act requires that we determine whether any species is an endangered species or a threatened species because of any of the following factors:

(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.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term ''threat'' to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term ''threat'' includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term ''threat'' may either encompass—together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an ''endangered species'' or a ''threatened species.'' In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, and then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the definition of an endangered species or a threatened species only after conducting this cumulative analysis and describing the expected effect on the species now and within the foreseeable future.

Foreseeable Future

The Act does not define the term ''foreseeable future,'' which appears in the statutory definition of ''threatened species.'' Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term foreseeable future extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. Reliable does not mean certain; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a

prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

When considering the future condition of emperor penguins, climate change is projected to be the most substantial threat to emperor penguins across the species' range. Determining a future time horizon for assessing plausible climate change-driven impacts is complicated by the variation in magnitude of change in climate variables projected further into the future. Uncertainty in century-scale projections of Earth's climate stems from a few main sources, in addition to model imperfections. In the near term, natural climate variability is the largest source of uncertainty in climate projections. Over multi-decadal timescales (approximately the next 30 to 50 years), uncertainties among climate model outputs tend to be most influenced by our imperfect scientific knowledge of the climate system. Over longer timescales (approximately the next 60 to 100 years), human actions and decisions affecting global greenhouse gas (GHG) emissions are considered to be the largest source of uncertainty in climate projections (Terando et al. 2020, pp. 14–15). Climate models used in national and global assessments simulate plausible and realistic representations of Earth's climate, but variations of initial conditions or model parameters and differences in how the models are developed and configured causes variation in model outputs, and ultimately affects the sensitivity of any given model to changes in atmospheric GHG concentrations (Terando et al. 2020, p. 14).

Atmospheric concentrations of GHG emissions in the near- and mid-term are determined primarily by current emissions and the average time it takes emitted molecules to break down chemically in the atmosphere. In the long term, human choices regarding economic development, changes in technology, and population trends will determine emission levels (Terando et al. 2020, p. 15).

The reliability of modeled projections of sea ice in the Southern Ocean using Global Circulation Models (GCMs) from the Coupled Model Intercomparison Project (CMIP) is an important issue (Trathan et al. 2020, p. 5; Roach 2020, entire). The amount of sea ice has exhibited minimal positive trends from 1979 to 2018; however, nearly all individual models simulate declining sea ice over this period (Roach 2020, entire). The existing models often do not capture the regional and, in some cases, opposing trends observed by satellites, and no single model matches the historical conditions at all colonies in all seasons. Thus, there is lower confidence in projections of Antarctic sea ice because of the wide range of outputs, and models not being able to replicate historical satellite observations, as well as multiple factors and complex interactions between the ocean and atmosphere that affect the Antarctic ice sheet (Meredith et al. 2019, pp. 205, 223). However, models continue to improve their ability to represent historical sea-ice conditions in Antarctica.

The key statutory difference between a threatened species and an endangered species is the timing of when a species may be in danger of extinction, either now (endangered species) or within the foreseeable future (threatened species). In the emperor penguin SSA, we considered time horizons at mid-century, late-century, and end-of-century (2050, 2080, 2100) for analyzing the future condition of emperor penguins. The population projections of emperor penguins are based on Intergovernmental Panel on Climate Change (IPCC) climate-change-model projections following available IPCC scenarios, using GCMs from (CMIP) phase 3 (CMIP3) and phase 5 (CMIP5).

When applying the information in the SSA to a listing context in considering what is the foreseeable future for emperor penguins, the projections of the global emperor penguin population begin to diverge around 2050. At 2050, population projections from all scenarios are within 50,000 pairs of each other (see figure A2 in the SSA report (Service 2021, p. 83). The differences in population estimates grows to approximately 150,000 breeding pairs by 2100, with scenario based on Representative Concentration Pathway (RCP) 8.5 predicting near extinction while the scenarios based on the Paris Accord commitments predict gradual declines that do not fall under 135,000 breeding pairs. Thus, after 2050, the variation in population size results in too much uncertainty for the Service to make reliable predictions on whether the emperor penguin's response to the threat of climate change will result in the species being in danger of extinction or not.

Climate change is the most substantial threat to emperor penguins in the future because of an increase in air and sea temperatures that negatively affects sea ice habitat and, relatedly, prey abundance in Antarctica. Most of the difference between the present climate and the climate at the end of the century and beyond will be determined by decisions made by policymakers today and during the next few decades (Terando et al. 2020, p. 15). At this time, we have little clarity on what decisions will be made by policymakers in the next few decades. Thus, we determined the projections of sea-ice conditions and the response of emperor penguins at the late-century and end-of-century (2080 and 2100) time horizons to be too uncertain to make reliable predictions. The 2050 time horizon extends only so far into the future as the Service can reasonably determine that both the future threats and the species' response to those threats are likely. Therefore, in this evaluation, we identified mid-century (2050) as the foreseeable future for the threat of climate change because that is the period over which we can make reliable predictions as to sea ice and the future condition of emperor penguins.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent a decision by the Service on whether the emperor penguin should be proposed for listing as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS–HQ–ES–2021–0043 on *http://www.regulations.gov.*

To assess the emperor penguin's viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example,

wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events (for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the species' ecological requirements for survival and reproduction at the individual, population, and species levels, and described the beneficial and risk factors influencing the species' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual species' life-history needs. The next stage involved an assessment of the historical and current condition of the species' demographics and habitat characteristics, including an explanation of how the species arrived at its current condition. The final stage of the SSA involved making predictions about the species' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the species and its resources, and the threats that influence the species' current and future condition, in order to assess the species' overall viability and the risks to that viability.

We used the SSA framework to evaluate the current biological status of emperor penguins at mid-century, late-century, and end-of-century (years 2050, 2080, and 2100). Because of the uncertainty about the magnitude of climate change at late-century (2080) and end-of-century (2100) time horizons, we were unable to make reliable predictions about the emperor penguin's response for the latter half of the century. Although the SSA report contains information on modeling results out to 2100, this proposed rule focuses on the threat of climate change and the emperor penguin's response to that threat at mid-century. Therefore, we focus on the 2050 timeframe as the foreseeable future for this proposed rule (see *Foreseeable Future,* above, for more information on how we determined the foreseeable future).

Species Needs/Ecological Requirements

The SSA contains a detailed discussion of the emperor penguin's individual and population requirements (Service 2021, pp. 14–27); we provide a summary here.

Emperor penguins rely on annual, stable fast ice to form breeding colonies; pack ice (belt of sea ice comprising ice floes of varying sizes that drifts in response to winds, currents, or other forces) and polynyas to forage; sufficient prey resources year round; and areas of sea ice to haul out, molt, rest, and avoid predation (Williams 1995, pp. 157–159; Ainley et al. 2010, p. 51; Trathan et al. 2020, p. 3). Polynyas are regions of biologically productive open water surrounded by ice and provide prime foraging habitat for emperor penguins because they often provide the closest open water to a colony (Labrousse et al. 2019, p. 2; NSIDC 2020, unpaginated).

Emperor penguins are meso-predators near the top of the Southern Ocean's food web (Cherel and Kooyman 2008, p. 2). They hunt opportunistically and shift foraging strategies relative to prey abundance and distribution (Trathan et al. 2020, p. 3; Williams 1995, p. 155). The life histories of emperor penguins and their primary prey species (*e.g.,* Antarctic silverfish (*Pleurogramma antarctica*) and Antarctic krill (*Euphausia superba*)) are tied to sea-ice extent and duration, and reproductive success of emperor penguins is highly dependent on foraging success. Thus, the interaction of demographic processes of reproduction and survival drives the population dynamics of emperor penguins, which are all related to the sea-ice environment.

Factors Influencing Viability of Emperor Penguins

Based on emperor penguin's life history and habitat needs, and in consultation with species' experts, we identified the stressors likely to affect the species' current and future condition and overall viability, as well as the sources of the stressors, and the existing conservation and regulatory measures that address certain stressors. For a full description of our evaluation of the effects of these stressors, refer to the SSA report (Service 2021, pp. 27–45).

Climate Change

Climate change presents the most substantial threat facing emperor penguins. Other stressors on the species include tourism and research, contaminants and pollution, and commercial Antarctic krill fisheries, but these stressors are minor and not considered to be driving factors of the emperor penguin's viability now or in the future. See the SSA report for a review of the minor threats (Service 2021, pp. 40–45).

Climate change is a change in the state of the climate that can be identified (*e.g.,* by using statistical tests) by changes in the mean and/or the variability of its properties and that persists for an extended period, typically decades or longer. Climate change may be due to natural internal processes or external forcings, which refers to an agent outside the climate system causing a change in the climate system, such as modulations of the solar cycles or volcanic eruptions, or to persistent anthropogenic changes in the composition of the atmosphere (*e.g.,* GHG emissions) or in land use (IPCC 2014a, pp. 120, 123).

Earth's climate has changed throughout history, and substantial regional variation exists in observations and projections of climate change impacts (IPCC 2014b, p. 1137). The current global warming trend is significant and most of it is extremely likely to be the result of humans adding heat trapping greenhouse gases to the atmosphere (IPCC 2014a, pp. 4–5; NASA 2020, unpaginated). Anthropogenic GHG emissions have increased since the pre-industrial era, largely because of technology and economic and population growth. This increase has led to atmospheric concentrations of carbon dioxide, methane, and nitrous oxide that are unprecedented in at least the last 800,000 years (IPCC 2014a, p. 4). The planet's average surface temperature has risen about 0.9 degrees Celsius (°C) (1.62 degrees Fahrenheit (°F)) since the late 19th century, with most of the warming occurring in the past 35 years and with the 6 warmest years on record taking place since 2014 (NASA 2020, unpaginated).

The Antarctic continent has seen less uniform temperature changes over the past 30–50 years, compared to the Arctic, and most of Antarctica has yet to see dramatic warming (Meredith et al. 2019, p. 212). The Antarctic Peninsula juts out into warmer waters north of Antarctica and is one of the fastest warming places on Earth, warming 2.5 °C (4.5 °F) since 1950 (Meredith et al. 2019, p. 212). However, warming has slowed on the peninsula since the late-1990s; this variability is within the bounds of large natural decadal-scale regional climate variability (Turner et al. 2016, p. 7; Stroeve 2021, pers. comm.).

In East Antarctica, no clear trend has emerged, although locations where some research stations occur appear to be cooling slightly (NSIDC 2020, unpaginated).

The magnitude of climate change into the future depends in part on the amount of heat-trapping gases emitted globally and how sensitive Earth's climate is to those emissions, as well as any human responses to climate change by developing adaptation and mitigation policies (NASA 2020, unpaginated; IPCC 2014a, p. 17).

Sea ice is sensitive to both the atmosphere and ocean; thus, it is an important indicator of polar climate changes (Hobbs et al. 2016, p. 1543). Given the influence that weather and climate have in affecting the extent and duration of sea ice and, relatedly, prey abundance around Antarctica, climate change is a substantial potential threat facing emperor penguins. Changes in sea-ice extent and duration, due to climate change, is projected to affect the emperor penguin's long-term viability at breeding colonies throughout the species' range. Different aspects of atmospheric circulation influence the annual sea-ice extent around Antarctica (Turner et al. 2015, pp. 5–8). Thus, climate change is not projected to have a uniform effect on the sea ice around the continent (Ainley et al. 2010, p. 56; Jenouvrier et al. 2014a, entire). Because sea ice in some regions of Antarctica are projected to be more affected than in other regions, emperor penguins and their breeding habitat around the continent will be affected at different magnitudes and temporal scales.

Unique to Antarctica is calving of huge, tabular icebergs, a process that can take a decade or longer by which pieces of ice break away from the terminus of a glacier (NSIDC 2020, unpaginated). On a stable ice shelf, iceberg calving is a near-cyclical, repetitive process producing large icebergs every few decades. These events are part of the natural system and not a good indicator of warming or climate change (NSIDC 2020, unpaginated). However, warmer temperatures can destabilize this system. Rapid ice-shelf collapse is attributed to warmer air and water temperatures, as well as increased melt on the ice surface (NSIDC 2020, unpaginated). Rapid collapse of ice shelves or calving of icebergs can affect emperor penguins, which mostly breed on fast ice at continental margins. Generally, catastrophic ice-shelf collapse or iceberg calving could cause mortality of chicks and adults, destroy a breeding colony resulting in total breeding failure, and prevent adult penguins from reaching their feeding ground affecting survival and reproductive success. For example, in March 2000, an iceberg from the Ross Ice Shelf calved and lodged near the Cape Crozier and Beaufort Island colonies in the Ross Sea, which caused habitat destruction, mortality of adults and chicks, and blocked access to foraging areas (Kooyman et al. 2007, p. 31). The effect would depend on the time of year (season) and the breeding colony's proximity to a collapsing ice shelf or calving iceberg (Fretwell and Trathan 2019, pp. 3–6; Kooyman et al. 2007, pp. 36–37). If a catastrophic event occurs, emperor penguins have been known to try to return to that same breeding location or relocate to another nearby site. However, this results in a loss of at least one breeding season for those birds because they may not find an alternate site that season.

The effect of climate change on prey abundance, relative to changes in sea ice, for emperor penguin and other marine life in the Southern Ocean could be substantial. However, the effect of climate change on Southern Ocean pelagic primary production is difficult to determine given that the time series data are insufficient (less than 30 years) to attribute a climate-change signature and effects may be due to a combination of climate change and natural variability (Meredith et al. 2019, p. 230; Ainley et al. 2010, p. 63). Nevertheless, the emperor penguin's primary prey species are positively tied to local sea-ice conditions and the penguin's breeding success is highly dependent on its foraging success. Therefore, subsequent distresses to the food web because of changes in sea ice increase the risk to emperor penguins over the long term.

Conservation Efforts and Regulatory Mechanisms

Antarctica is designated as a natural reserve devoted to peace and science under the Protocol on Environmental Protection to the Antarctic Treaty (Protocol) that was signed in 1991 and entered into force in 1998 (Secretariat of the Antarctic Treaty 2020, unpaginated). The Protocol includes annexes with measures to minimize effects to the Antarctic environment from conduct related to activities in Antarctica such as national program operations, scientific research, tourism, and other non-governmental activities. The Antarctic Treaty System (see United States Treaties and Other International Agreements (UST): 12 UST 794; Treaties and Other International Acts Series (TIAS): TIAS 4780; and the United Nations Treaty Series (UNTS): 402 UNTS 71), first signed in 1959 by 12 nations, regulates international relations with respect to Antarctica. Fifty-four countries have acceded to the Treaty, and 29 of them participate in decision making as Consultative Parties. Protection of the Antarctic environment has been a central theme in the cooperation among Parties (Secretariat of the Antarctic Treaty 2020, unpaginated).

Under the Protocol, certain protected areas have been established to protect outstanding environmental, scientific, historic, aesthetic or wilderness values, any combination of those values, or ongoing or planned scientific research. Additionally, marine-protected-area boundaries may include ice shelves, adjacent fast ice and pack ice, and potentially afford more complete protection for emperor penguins at their breeding site and while feeding or molting at sea than protected areas that are land based (Trathan et al. 2020, p. 7). To date, seven active breeding sites are protected within protected areas and seven are protected by the Ross Sea region marine protected area, including three colonies that are also in protected areas (Trathan et al. 2020, p. 8) The management plans for these areas explain specific concerns about emperor penguins (Secretariat of the Antarctic Treaty 2020, unpaginated).

In the United States, the Antarctic Conservation Act of 1978 (16 U.S.C. 2401 *et seq.*) (ACA) also provides for the conservation and protection of the fauna and flora of Antarctica (defined to mean the area south of 60 °S latitude (16 U.S.C. 2402)), and of the ecosystem upon which those fauna and flora depend, consistent with the Antarctic Treaty and the Protocol. The ACA's implementing regulations (45 CFR part 670) include provisions relating to the conservation of Antarctic animals, including native birds such as emperor penguins.

Additionally, the Convention on the Conservation of Antarctic Marine Living Resources (Convention) (33 UST 3476; TIAS 10240), which establishes the Commission for the Conservation of Antarctic Marine Living Resources (Commission), provides for the conservation and rational use of marine living resources in the Convention area. The Commission was established in 1982, with the objective of conserving Antarctic marine life, in response to increasing commercial interest in Antarctic krill resources and a history of over-exploitation of several other marine resources in the Southern Ocean (Commission 2020, unpaginated). Twenty-five countries plus the European Union are party to the Convention, with another 10 countries

also having acceded (Commission 2020, unpaginated). The United States implemented the Commission through the Antarctic Marine Living Resources Convention Act of 1984 (16 U.S.C. 2431 *et seq.*) (AMLRCA). Under the AMLRCA, among other prohibitions, it is unlawful to: (1) Engage in harvesting or other associated activities in violation of the provisions of the Convention or in violation of a conservation measure in force with respect to the United States; and (2) ship, transport, offer for sale, sell, purchase, import, export, or have custody, control or possession of, any Antarctic marine living resource (or part or product thereof) harvested in violation of a conservation measure in force with respect to the United States (16 U.S.C. 2435).

The regulatory mechanisms and conservation efforts focus on the native marine and terrestrial resources of Antarctica. The existing mechanisms minimize environmental impacts to emperor penguins from national program operations, scientific research, tourism, and other non-governmental activities in Antarctica. None of the existing regulatory mechanisms addresses the primary and unique nature of the threat of climate change on emperor penguins; however, we recognize the value these regulatory mechanisms and conservation efforts play in helping to conserve the species.

Current Condition

The current condition of emperor penguin is based on population abundance (*i.e.,* number of breeding pairs) at each colony and the global abundance distributed throughout the species' range. The resiliency of each emperor penguin colony is tied to local sea-ice conditions because the species depends on sea ice that offers a breeding platform to complete its annual breeding cycle and promotes primary production. As sea ice melts in the summer, it releases algae and nutrients into the water that stimulate phytoplankton blooms, which play a key role in the Southern Ocean food web (Hempel 1985, in Flores et al. 2012, p. 4). Therefore, the estimates of sea-ice condition and the emperor penguin population are directly related, and sea ice serves as a proxy measure of all important habitat factors for the species. Sea ice surrounding Antarctica is described within five sectors (Weddell Sea, Indian Ocean, Western Pacific Ocean, Ross Sea, and Bellingshausen Sea-Amundsen Sea) (figure 2), which may approximately correspond to the known genetic variation among colonies and the Southern Ocean as a whole.

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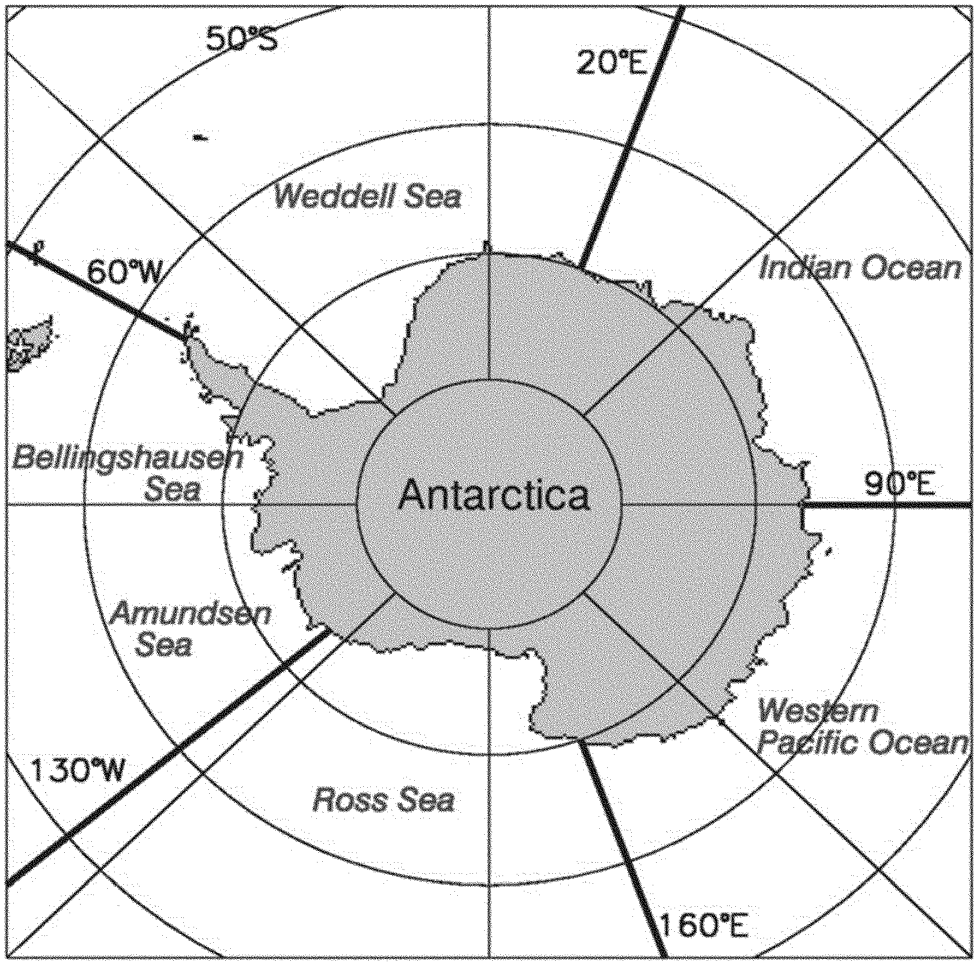

Figure 2. Image showing the five sectors of Antarctica: Weddell Sea (60 °W–20 °E), Indian Ocean sector of the Southern Ocean (20 °E–90 °E), Western Pacific Ocean sector of the Southern Ocean (90 °E–160 °E), Ross Sea (160 °E–130 °W), and the Bellingshausen Sea-Amundsen Sea (130 °W–60 °W).

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As of 2020, 61 emperor penguin breeding colonies are extant. Of the 66 total known colonies, four were not extant or not visible in the 2019 satellite imaging, 1 colony is extirpated, and 11 of the colonies were newly discovered or rediscovered in 2019. The global population comprises approximately 270,000–280,000 breeding pairs or 625,000–650,000 individual birds. The Ross Sea and Weddell Sea sectors contain the highest abundance of birds relative to the other three sectors.

In the Southern Ocean, sea-ice extent undergoes considerable inter-annual variability, although with much greater inter-annual variability regionally than for the Southern Ocean as a whole (Parkinson 2019, p. 14414). Sea-ice extent in the Southern Ocean is currently within its natural range of variability. Over the 40 years from 1979 to 2018, the yearly sea-ice extent in the Southern Ocean has a small, but statistically insignificant, positive trend. However, this overall increase masks larger and sometimes opposing regional differences in trends (Turner et al. 2015, pp. 1–2; Parkinson 2019, p. 14419). The greatest increase in sea ice extent has been in the Ross Sea sector, with smaller increases in the Weddell Sea and along the coast of East Antarctica, and a decrease in the Bellingshausen Sea and Amundsen Sea in West Antarctica (Turner et al. 2015, p. 9; Holland 2014, in Meredith et al. 2019, p. 214; Parkinson 2019, entire). The satellite record reveals that the gradual, decades-long overall increase in Antarctic sea-ice extent reversed in 2014, with subsequent rates of decrease in 2014–2018. All sectors, except the Ross Sea, have experienced at least one period since 1999 when the yearly average sea-ice extent decreased for 3 or more consecutive years only to rebound again, and eventually reach levels exceeding the sea-ice extent preceding the 3 years of decreases. Therefore, recent decreases in sea ice may not indicate a long-term negative trend (Parkinson 2019, p. 14420).

Emperor penguins may have difficulties finding food in years of low sea ice, which may increase adult mortality and reduce breeding success. Currently, prey abundance appears not to be a limiting factor for emperor penguins.

The emperor penguin currently has high resiliency, redundancy, and representation. Sixty-one breeding colonies are distributed around the coastline of Antarctica with no indication that their distribution has decreased or is presently decreasing. The number of known breeding colonies has increased over time, because the use of satellite imagery has improved the ability to locate colonies and roughly estimate population sizes at colonies. Catastrophic events may include iceberg calving, ice-shelf disintegration, and storm events. However, if a catastrophic event occurs, it only affects a small proportion of the total breeding colonies at any one time, and the displaced penguins try to return to that same breeding location or relocate to another nearby colony. Breeding colonies within the four known metapopulations have some degree of connectivity among metapopulations and very high connectivity between breeding colonies within each of the metapopulations. Two of the four metapopulations are in East Antarctica (Mawson Coast and Amanda Bay/Point Géologie metapopulations) while the other two are the Weddell Sea metapopulation and the Ross Sea metapopulation (Younger et al. 2017, p. 3892). There has been no loss of the known metapopulations.

Future Condition

The interaction of demographic processes of reproduction and survival drives the population dynamics of the emperor penguin, which are all related to the sea-ice environment. Therefore, to project the long-term viability of emperor penguin, the sea-ice extent and/or concentration and how it relates to the emperor penguin's long-term demographics has been modeled under different climate change scenarios (Ainley et al. 2010, entire; Jenouvrier et al. 2009, 2012, 2014, 2017, 2020). The research into emperor penguin populations and their habitat conditions uses an ensemble of climate models based on changes in sea ice into the future that is founded on standard climate modeling efforts (*e.g.,* Ainley et al. 2010; Jenouvrier et al. 2009, 2012, 2014, 2017, 2020; Melillo et al. 2014).

The future scenarios for population projections of emperor penguins are based on climate change model projections following available IPCC scenarios using Global Circulation Models driven by Special Report on Emissions Scenarios (SRES) and by Representative Concentration Pathways (RCP) scenarios (Hayhoe et al. 2017, p. 142).

Modeling efforts projected sea-ice conditions and the emperor penguin's response under low-, moderate-, and high-emissions scenarios. The Paris Agreement set a goal to limit global warming to below 2 °C and preferably to 1.5 °C, compared to pre-industrial levels (United Nations 2021, unpaginated). The Paris Agreement goals (low-emissions scenario) do not represent or equate to any RCP scenario; they are uniquely designed to meet the global temperature change targets set in the Paris Agreement (Sanderson and Knutti 2016, in Jenouvrier et al. 2020, p. 1; Sanderson et al. 2017, p. 828). The global temperature is likely to increase 0.3–1.7 °C under RCP 2.6, and 1.0–2.6 °C under RCP 4.5 (IPCCb 2019, p. 46). Therefore, based strictly on the projected increase in global temperature, the Paris Agreement goals would fall within the projected range of RCP 2.6 and RCP 4.5 projections. Thus, we view the two projections aligned with the Paris goals collectively as one low-emissions scenario. We also evaluated two moderate-emissions scenarios: One in which the global temperature is projected to increase up to 2.6 °C under RCP 4.5, and a second in which the global temperature is projected to increase up to 3.2 °C by the end of the century (SRES A1B). Finally, we used a high-emissions scenario (RCP 8.5) with the greatest warming where global temperature is projected to increase up to 4.8 °C (IPCC 2019b, p. 46).

Given the complexities of Global Circulation Models and advancements in technology, models typically build upon previous modeling efforts. The modeling for the global population of emperor penguins and sea-ice conditions was initially run under scenario SRES A1B in CMIP3 using the best available information of the population and demographics at the time. SRES A1B in CMIP3 is consistent with RCP 6.0 in CMIP5 (Melillo et al. 2014, p. 755). As newer models were developed, and experts learned more about emperor penguin dispersal capabilities and behavior and discovered more colonies that increased the global population size, the modeling efforts were refined to account for additional colonies and inter-colony dispersal behaviors. Additionally, the most recent projections for the emperor penguin include simulations that account for extreme or catastrophic events occurring in Antarctica (Jenouvrier et al. 2021, in litt.).

The Community Earth System Model Large Ensemble project was used in the most recent modeling efforts to simulate the sea-ice conditions, building upon the initial efforts of the moderate-emissions scenario SRES A1B, which used models that contributed to CMIP3. The Community Earth System Model contributed to CMIP5 and was included in the IPCC fifth assessment report (Jenouvrier et al. 2020, pp. 3–4). The largest differences between the Community Earth System Model

compared to historical sea-ice conditions occur in the nonbreeding season, which has a small influence on emperor penguin population growth rates. Sea-ice conditions during the laying season have the greatest effect on the population growth rates, and those conditions are well addressed in this model (Jenouvrier et al. 2020, p. 7). The sea-ice models relied on for the SSA report represent the best available scientific information.

The demographic parameters for emperor penguin used for all colonies are based on, and extrapolated from, the population at Pointe Géologie in Terre Adélie (see figure 1, colony #35) because the vast majority of colonies have not been visited or subject to long-term studies. Sea ice-condition is projected to decrease in Antarctica and emperor penguins will likely need to disperse or attempt to disperse as colonies are disrupted or lost due to sea-ice instability. The simulations in the latest unpublished models include emperor penguin dispersal behaviors and extreme or catastrophic events, and we find including these additional demographic factors is an improvement because they represent natural and observed parts of the emperor penguin's relationship to the sea-ice environment. See the SSA report for a more thorough discussion of the demographic uncertainties in century-scale projections of climate change as they relate to emperor penguins (Service 2021, pp. 56–57, 80–82).

Low-Emissions Scenario

Under the low-emissions scenario, the median global population of emperor penguins is projected to decline by 26 percent under Paris 1.5, and by 27 percent under Paris 2.0 by 2050. At that point, approximately 185,000 breeding pairs would remain. However, the declines would not occur equally around the continent. Colonies in the Ross Sea and Weddell Sea are likely to experience more stable conditions. Colonies in the Ross Sea are projected to increase from their current size by 2050, as penguins from other areas with less suitable habitat migrate to the Ross Sea. Colonies in the Weddell Sea are projected to increase initially; however, by 2050, the population is projected to be slightly smaller than the current population size in this sector. Colonies in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors are projected to decline the most. By 2050, colonies within these three sectors are projected to decline by at least 50 percent, but the vast majority are projected to decline by more than 90 percent.

Moderate-Emissions Scenarios

For simulations under one of the moderate-emissions scenarios, SRES A1B in CMIP3, the population growth rate is projected to be slightly positive until 2050, while the median global population is projected to decline by 19 to 33 percent by 2100 (Jenouvrier et al. 2014a, p. 716; Jenouvrier et al. 2014b, p. 28). We note this projection is at 2100 and we do not have an estimate of the global population or population size within each sector at 2050. Under the other moderate-emissions scenario, RCP 4.5, the global population is projected to decline by 33 percent by 2050 (to approximately 167,000 breeding pairs; Jenouvrier et al. 2021, in litt.). Similar to the projections under the low-emissions scenario, the declines are not equal around the continent. The Ross Sea and Weddell Sea experience the smallest decrease in breeding pairs. However, even high-latitude colonies in the Ross Sea and Weddell Sea are not immune to changes in sea-ice condition under this scenario (Jenouvrier et al. 2014, entire; Schmidt and Ballard 2020, pp. 183–184). The vast majority, and possibly all, colonies in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors are projected to decline by more than 90 percent. Two important differences in the results of the two moderate-emissions scenarios are noteworthy: The projections under SRES A1B were modeled using a different model and method than all the other scenarios, and the projections under RCP 4.5 include demographic factors of dispersal and extreme events while SRES A1B projections do not. Dispersal behaviors may accelerate, slow down, or reverse the anticipated rate of population decline of emperor penguins, compared to the population projection without dispersal considered, but does not change the overall conclusion that the global population will decline. Extreme events are projected to increase the magnitude of decline throughout the species' range.

High-Emissions Scenario

Under the high-emissions scenario, RCP 8.5, the global population of emperor penguin is projected to decline 47 percent by 2050 (to approximately 132,500 breeding pairs; Jenouvrier et al. 2021, in litt.). Similar to the low- and moderate-emissions scenarios, the declines are not equal around the continent. However, the population decline is greater in magnitude under the high-emissions scenario. The few colonies that are projected to remain occur in the Ross Sea and Weddell Sea. The breeding colonies in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors are projected to decline by more than 90 percent.

Resiliency, Redundancy, and Representation

The two most resilient sectors of Antarctica are first the Ross Sea and then the Weddell Sea under every emissions scenario. The breeding colonies in these sectors are projected to have the highest resiliency because these areas are likely to have the most stable long-term sea-ice conditions. The breeding colonies in the Indian Ocean sector are projected to be the least resilient, and experience the largest population declines and sea-ice decrease and variability under every scenario. The Bellingshausen Sea-Amundsen Sea sector is also projected to have low resiliency. Projected declines in the Western Pacific Ocean sector are more complex and vary according to emissions scenario; however, the colonies in this sector also markedly decline. Under the high-emissions scenario RCP 8.5, the vast majority of breeding colonies throughout the range decline significantly by 2050, resulting in the Ross Sea and Weddell Sea serving as the last refuges for the species.

Redundancy is higher under the low-emissions scenario than under the moderate- and high-emissions scenarios because more colonies remain extant under the low-emissions scenario. Under the high-emissions scenario, the colonies in the three least resilient sectors (Indian Ocean, Bellingshausen Sea-Amundsen Sea, and the Western Pacific Ocean) are predicted to decline substantially, if not disappear entirely, whereas under the other emissions scenarios some colonies are predicted to decline less appreciably in East Antarctica and in West Antarctica depending on the scenario. Including extreme events into the simulations increases the magnitude of declines at breeding colonies throughout the range under every scenario.

Representation is similar to redundancy in that it decreases as the distribution of the species declines. The emperor penguin is predicted to lose genetic diversity under every scenario because the overall population abundance is projected to decline. Under the low-emissions scenario with projections that do not include dispersal or extreme events, no known metapopulations are lost, although colonies that make up the two metapopulations in East Antarctica are projected to decline. However, when

including dispersal and extreme events, both of the metapopulations in East Antarctica along with many other colonies in East Antarctica and in the Bellingshausen Sea-Amundsen Sea sector for which genetics have not been analyzed are projected to decline by more than 90 percent by 2050.

Projections under the moderate-emissions scenarios show a similar pattern with an increase in magnitude of decline, which would also likely result in the loss of the two metapopulations in East Antarctica. Emperor penguins may migrate to the Ross Sea or Weddell Sea where some habitat is projected to remain suitable as habitat quality declines in the other sectors. However, the colonies that remain will likely reach carrying capacity, and some colonies provide little potential for population expansion (Jenouvrier et al. 2014, p. 716).

Under the high-emissions scenario, the emperor penguin would increasingly lose genetic diversity, because of declines in the Weddell Sea and Ross Sea, which account for the other two known metapopulations. Colonies within these two metapopulations would decrease in redundancy over time, thus reducing the genetic variation within the two metapopulations. The Ross Sea may be the last stronghold for the species, but even the number of breeding colonies in the Ross Sea have the potential to decline under the high-emissions scenario. Therefore, the genetic diversity of emperor penguins will substantially decrease under the high-emissions scenario because the vast majority of all colonies are likely to decline by more than 90 percent, or disappear entirely.

Summary

The emperor penguin is currently in high condition because the species has high resiliency, redundancy, and representation. Sixty-one breeding colonies are distributed around the coastline of Antarctica with no indication that there has been a decrease in their range or distribution. Colony size naturally fluctuates, and reproductive success varies from year to year at breeding colonies in relation to both biotic and abiotic factors. However, emperor penguins have high survival rates and reproductive success. Genetic analysis has identified four known metapopulations of emperor penguins, with many areas of Antarctica not yet analyzed.

Sea-ice extent in the Southern Ocean is currently within its natural range of variability. The yearly sea ice extent in the Southern Ocean has a small positive but statistically insignificant trend over the 40 years from 1979 to 2018, although the overall increase masks larger, opposing regional differences in trends. The emperor penguin's main prey resources are directly related to the extent and duration of sea ice. Currently, prey abundance appears not to be a limiting factor for emperor penguins.

The Antarctic continent has seen less uniform temperature changes over the past 30 to 50 years, compared to the Arctic, and most of Antarctica has yet to see dramatic warming. Weather and climate are projected to affect the extent and duration of sea ice and, relatedly, prey abundance in Antarctica. Therefore, climate change presents the most substantial threat facing emperor penguins in the future. Antarctica will be profoundly different in the future compared with today, but the degree of that difference will depend strongly on the magnitude of global climate change. The magnitude of climate change into the future depends in part on the amount of heat-trapping gases emitted globally and how sensitive the Earth's climate is to those emissions, as well as any human responses to climate change by developing adaptation and mitigation policies.

Under all scenarios, sea-ice extent and the global population of emperor penguins are projected to decline in the future; however, the degree and speed of the decline varies substantially by scenario. Accordingly, the resiliency, redundancy, and representation of the emperor penguin will also decrease across all scenarios. The rate and magnitude of decline of the sea-ice conditions and the number of breeding pairs and colonies of emperor penguins varies between scenarios, temporally and spatially. Breeding colonies in the Ross Sea and Weddell Sea sectors, the current strongholds for the species, are projected to retain the most resiliency and have the most stable sea-ice conditions into the future, relative to the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors. The projected decline in the global population of emperor penguins is much less under the low-emissions scenario (*i.e.,* the scenarios that model the Paris Accord) than under the high-emissions scenario (*i.e.,* RCP 8.5). Similarly, redundancy and representation are higher under the low-emissions scenarios compared to the high-emissions scenario because more colonies are projected to be extant. Redundancy and representation decline at a faster rate than resiliency because the Ross Sea and Weddell Sea sectors contain at least half the global population, have a greater initial population abundance compared to the other three sectors, and are projected to have higher-quality sea-ice habitat over a longer time period. These two sectors, and particularly the Ross Sea, are strongholds for the species under every scenario, as the other sectors markedly decline because sea-ice conditions deteriorate.

We note that, by using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects on the species, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the species. To assess the current and future condition of the species, we undertake an iterative analysis that encompasses and incorporates the threats individually and then accumulates and evaluates the effects of all the factors that may be influencing the species, including threats and conservation efforts. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire species, our assessment integrates the cumulative effects of the factors and replaces a standalone cumulative-effects analysis.

Determination of Emperor Penguin's Status

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an ''endangered species'' or a ''threatened species.'' The Act defines an ''endangered species'' as a species in danger of extinction throughout all or a significant portion of its range, and a ''threatened species'' as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of an endangered species or a threatened species because of any of the following factors: (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.

Status Throughout All of Its Range

After evaluating threats to the species and assessing the cumulative effect of the threats under the section 4(a)(1) factors, we found that climate change presents the most substantial threat to emperor penguin's viability. While other activities such as tourism and commercial fisheries occur on and near Antarctica, international regulatory measures are in place that adequately regulate conduct related to these activities in Antarctica. Thus, no other stressors are drivers of the species' viability.

The emperor penguin is currently in high condition because the species has high resiliency, redundancy, and representation. Emperor penguin breeding colonies are distributed around the continent (see figure 1, above) with no indication that their distribution or genetic or ecological diversity is presently decreasing. Sixty-one breeding colonies are extant. The global population comprises approximately 270,000–280,000 breeding pairs or 625,000–650,000 individual birds, with the greatest abundance in the Ross Sea and Weddell Sea sectors. Emperor penguins have high survival and reproductive success, and genetic analysis has identified four known metapopulations of emperor penguins.

The sea-ice conditions in Antarctica are described within five sectors (Weddell Sea, Indian Ocean, Western Pacific Ocean, Ross Sea, and Bellingshausen Sea-Amundsen Sea), and colonies within these sectors may approximately correspond to the genetic variation of the four known metapopulations (see figures 1 and 2, above). Sea-ice extent in the Southern Ocean serves as a proxy measure of all important habitat factors for emperor penguins. Sea-ice extent is currently within its natural range of variability. The yearly sea-ice extent in the Southern Ocean has a small positive, but statistically insignificant trend over the 40 years from 1979 to 2018, although the overall increase masks larger, and sometimes opposing regional differences in trends. The emperor penguin's main prey resources (Antarctic silverfish and Antarctic krill) are directly related to the extent and duration of sea ice. Currently, foraging success and prey availability appear not to be limiting factors for emperor penguins throughout their range.

Thus, after assessing the best available information, we determined that the emperor penguin is not currently in danger of extinction throughout all of its range. We then turned our attention to determining whether the emperor penguin is in danger of extinction throughout all of its range within the foreseeable future.

At 2050, roughly 50,000 breeding pairs constitute the difference between global population projections for the low- and high-emissions scenarios. Starting at approximately 250,000 breeding pairs, under Paris 1.5, the median number of breeding pairs declines to approximately 185,000, and under RCP 8.5, the median number of breeding pairs declines to approximately 132,500.

The Ross Sea and Weddell Sea sectors currently contain the greatest abundance of emperor penguin breeding pairs and are projected to be the most resilient sectors within the foreseeable future, relative to the Indian Ocean, Western Pacific Ocean, and Bellingshausen Sea-Amundsen Sea sectors. Redundancy and representation decline at a faster rate than resiliency because the Weddell Sea, and particularly the Ross Sea, are the strongholds for the species as the colonies in the other sectors markedly decline because sea-ice conditions are projected to deteriorate. Assessing the results of the projections for all scenarios shows that the majority of the remaining global population would be in the Weddell Sea and Ross Sea sectors. These two sectors contain two of the four known metapopulations (Weddell Sea and Ross Sea metapopulations) and are the two most resilient sectors.

The global population at 2050 is projected to decline between 26 percent (to approximately 185,000 breeding pairs) and 47 percent (to approximately 132,500 breeding pairs) under the low- and high-emissions scenarios, respectively. The global population would be large enough and retain sufficient viability so that the species is not in danger of extinction by 2050, because the breeding pairs remaining include at least 50 percent of the global breeding pairs, even under the high-emissions scenario. That said, the distribution of the species will be reduced by 2050 because most, and possibly all, colonies and breeding pairs will be limited to the Weddell Sea and Ross Sea sectors; almost the entire decline of breeding pairs is because of the loss of breeding colonies in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors. However, enough breeding colonies would be extant in the Weddell Sea and Ross Sea to withstand localized stochastic and catastrophic events. The genetic and ecological diversity of emperor penguins will be reduced because the decrease in distribution of breeding colonies results in the loss of the colonies that make up the two metapopulations in East Antarctica (Mawson Coast and Amanda Bay/Point Géologie metapopulations), and many other colonies in East Antarctica and in the Bellingshausen Sea-Amundsen Sea sector for which breeding colony genetics have not been analyzed. The Weddell Sea and Ross Sea sectors contain the other two metapopulations that maintain genetic and ecological diversity, are the strongholds for the species, and are projected to contain the vast majority, and possibly all, the remaining breeding colonies at 2050. The emperor penguin will decrease in resiliency, representation, and redundancy compared to current conditions. However, the global population size at 2050 will be large, and enough colonies will be extant in the Weddell Sea and Ross Sea, such that the species as a whole will not likely to be in danger of extinction.

Thus, after assessing the best available information, we conclude that the emperor penguin is not likely to become in danger of extinction within the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so within the foreseeable future throughout all or a significant portion of its range. Having determined that the emperor penguin is not in danger of extinction or likely to become so within the foreseeable future throughout all of its range, we now consider whether the emperor penguin is in danger of extinction or likely to become so within the foreseeable future in a significant portion of its range—that is, whether there is any portion of the species' range for which it is true that both (1) the portion is significant; and (2) the species, in that portion, is in danger of extinction or likely to become so within the foreseeable future. Depending on the case, it might be more efficient for us to address the ''significance'' question or the ''status'' question first. We can choose to address either question first. Regardless of which question we choose to address first, if we reach a negative answer with respect to the first question, we do not need to evaluate the other question for that portion of the species' range.

For the emperor penguin, sea-ice conditions in Antarctica are described in five sectors, which also may approximately correspond to the known

genetic variation among breeding colonies. Emperor penguins are distributed around the entire coastline of Antarctica, and we assessed the status of the species in relation to the five sectors. Therefore, to assess the significance and status questions, we consider emperor penguins to occur within five sectors.

We chose to first address the status question—we consider information pertaining to the geographic distribution of both the species and the threats that the species faces to identify any portions of the range where the species is endangered or threatened. We considered whether the threat of climate change is geographically concentrated in any portion of the species' range at a biologically meaningful scale. Climate change is not projected to have a uniform effect around the entire continent of Antarctica; the rate and magnitude of decline of sea-ice conditions and breeding colonies vary temporally and spatially. It is in this context that we considered the concentration of threats of climate change to the emperor penguin.

We found that climate change is projected to substantially affect the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors under every modeled emissions scenario within the foreseeable future. The Ross Sea and Weddell Sea sectors are considered strongholds for the species now and into the foreseeable future because they have the most stable long-term sea-ice condition. However, projections under low-, moderate-, and high-emissions scenarios result in a substantial decline of the breeding colonies and sea-ice condition in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors. By 2050, the colonies within these three sectors decline rather quickly and are projected to decline by at least 50 percent, with the vast majority projected to decline by more than 90 percent under every scenario.

Currently, breeding colonies are distributed along the entire coastline of Antarctica with no gaps larger than 500 kilometers (311 miles) between colonies, except in front of large ice shelves (see figure 1, above). By 2050, the global population of emperor penguins is projected to decline between 26 percent (to approximately 185,000 breeding pairs) and 47 percent (to approximately 132,500 breeding pairs); however, almost the entire decline of global breeding pairs is because of the loss of breeding colonies in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors. This results in a substantial decline of the population and distribution of breeding colonies in these three sectors. Therefore, because climate change is projected to affect the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors of the species' range more than the Ross Sea and Weddell Sea sectors, resulting in a substantial decline of the breeding colonies in these three sectors, the species may be in danger of extinction or likely to become so within the foreseeable future in this portion of its range.

We first considered whether the species was endangered in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean portion of the species' range. The emperor penguin is currently in high condition throughout its range (see *Status Throughout All of Its Range,* above). Therefore, the emperor penguin within these three sectors of its range is also currently in high condition, and the best scientific and commercial data available indicates that this portion of its range currently has sufficient resiliency, redundancy, and representation to be secure in its current state. Therefore, the emperor penguin is not currently in danger of extinction (endangered) in that portion of its range.

However, while the divergence in global population projections between the scenarios becomes more evident around 2050, under every scenario the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors are projected to substantially decline within the foreseeable future. The decline in the global population is almost entirely attributed to the decline of sea-ice conditions and loss of breeding colonies in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors. By 2050, breeding colonies within these three sectors decline by at least 50 percent, with the vast majority projected to decline by more than 90 percent. Therefore, the emperor penguin in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors will have minimal to no resiliency, distribution of breeding colonies, or genetic and ecological diversity because very few colonies and breeding pairs are projected to remain in this portion of the species' range by 2050. Thus, the species is likely to become in danger of extinction within the foreseeable future in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors.

We then proceeded to ask the question whether the portion of the range including the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors is significant. We assessed whether this portion of the species' range is biologically significant by considering it in terms of the portion's contribution to resiliency, redundancy, or representation of the species as a whole.

The Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors account for 40 to 50 percent of the global population, approximately 60 percent of the species' range and total number of known breeding colonies, and 50 percent of the known genetic diversity. Ecological diversity between breeding colonies in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors include breeding location (sea ice vs. ice shelf), distance to open water, exposure to katabatic winds (cold dense air flowing out from interior Antarctica to the coast), and amount of snowfall. Breeding colonies within the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors provide connectivity between colonies within the metapopulations and among the metapopulations in different sectors. Currently, it is likely that all breeding colonies are connected because the average distance between colonies throughout the species' range (500 kilometers (311 miles)) is well within the distance that emperor penguins can travel/disperse. The fact that emperor penguins travel widely as juveniles, move among breeding colonies, and share molting locations indicates that dispersal between breeding colonies provides gene flow among colonies (Thiebot et al. 2013, entire; Younger et al. 2017, p. 3894). If there were minimal to no breeding colonies (as projected) in the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors, the distance between colonies would substantially increase and reduce the probability that all colonies are connected and provide gene flow among colonies. Additionally, the diversity of the species and its habitat would substantially decrease because the vast majority of colonies that would remain (as projected) would only be in the Ross Sea and Weddell Sea sectors. The Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors contribute significantly to the emperor penguin's global population size (resiliency), global distribution around the entire coastline of Antarctica (redundancy), and genetic and ecological diversity (representation) of

the species as a whole, and the conservation of the species would suffer the loss of these significant contributions if these sectors were lost.

Therefore, having determined that the Indian Ocean, Bellingshausen Sea-Amundsen Sea, and Western Pacific Ocean sectors (or portion of the species' range) do indeed meet both of the significant portion of the range prongs ((1) the portion is significant; and (2) the species is, in that portion, likely to become in danger of extinction within the foreseeable future), the emperor penguin is in danger of extinction within the foreseeable future within a significant portion of its range. This is consistent with the courts' holdings in *Desert Survivors* v. *Department of the Interior,* No. 16–cv–01165–JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity* v. *Jewell,* 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that the emperor penguin meets the definition of a threatened species. Therefore, we propose to list the emperor penguin as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

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 activities. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, foreign governments, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or 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)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, 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 the 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.

An ''action'' that is subject to the consultation provisions of section 7(a)(2) is defined in our implementing regulations at 50 CFR 402.02 as ''all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas.'' With respect to the emperor penguin, there are no ''actions'' known to require consultation under section 7(a)(2) of the Act, and it is therefore unlikely to be the subject of section 7 consultations. Additionally, no critical habitat will be designated for this species because, under 50 CFR 424.12(g), we will not designate critical habitat within foreign countries or in other areas outside of the jurisdiction of the United States.

Section 8(a) of the Act (16 U.S.C. 1537(a)) authorizes the provision of limited financial assistance for the development and management of programs that the Secretary of the Interior determines to be necessary or useful for the conservation of endangered or threatened species in foreign countries. Sections 8(b) and 8(c) of the Act (16 U.S.C. 1537(b) and (c)) authorize the Secretary to encourage conservation programs for foreign listed species, and to provide assistance for such programs, in the form of personnel and the training of personnel.

As explained below, the proposed 4(d) rule for the emperor penguin would, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export; deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any emperor penguins. It would also be illegal to take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or to attempt any of these) within the United States or on the high seas; or to possess, sell, deliver, carry, transport, or ship, by any means whatsoever any emperor penguins that have been taken in violation of the Act. It would also be unlawful to attempt to commit, to solicit another to commit or to cause to be committed, any of these acts. Certain exceptions apply to agents of the Service and State conservation agencies. Additional exceptions are also provided in the proposed 4(d) rule for activities permitted under the Antarctic Conservation Act of 1978, as amended (16 U.S.C. 2401 *et seq.*), and its implementing regulations (45 CFR part 670), including for take and possession of emperor penguins within Antarctica, and for import and export of emperor penguins between the United States and Antarctica. An exception is also proposed for interstate commerce from public institutions to other public institutions, specifically museums, zoological parks, and scientific or educational institutions that meet the definition of ''public'' at 50 CFR 10.12.

We may issue permits to carry out otherwise prohibited activities involving endangered and threatened wildlife species under certain circumstances. Regulations governing permits for threatened species are codified at 50 CFR 17.32, and general Service permitting regulations are codified at 50 CFR part 13. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act. The Service may also register persons subject to the jurisdiction of the United States through its captive-bred-wildlife (CBW) program if certain established requirements are met under the CBW regulations (50 CFR 17.21(g)). Through a CBW registration, the Service may allow a registrant to conduct the following otherwise prohibited activities under certain circumstances to enhance the propagation or survival of the affected species: Take; export or re-import; deliver, receive, carry, transport, or ship in interstate or foreign commerce, in the course of a commercial activity; or sell or offer for sale in interstate or foreign commerce. A CBW registration may authorize interstate purchase and sale only between entities that both hold a registration for the taxon concerned. The CBW program is available for species having a natural geographic distribution not including any part of the United States and other species that the Service Director has determined to be eligible by regulation. The individual specimens must have been born in captivity in the United States. The statute also contains certain 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 proposed listing on proposed and ongoing activities within the range of the species proposed for listing. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy.

II. Proposed Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the Secretary shall issue such regulations as he or she deems necessary and advisable to provide for the conservation of species listed as threatened. The U.S. Supreme Court has noted that statutory language like necessary and advisable demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. Thus, the combination of the two sentences of section 4(d) provides the Secretary with broad discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife, or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him [or her] with regard to the permitted activities for those species. He [or she] may, for example, permit taking, but not importation of such species, or he [or she] may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising this authority under section 4(d), we have developed a proposed rule that is designed to address the emperor penguin's specific threats and conservation needs. Although the statute does not require us to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this proposed rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the emperor penguin.

As discussed above under Summary of Biological Status and Threats, and Determination of Emperor Penguin's Status, we have concluded that the emperor penguin is likely to become in danger of extinction within the foreseeable future primarily due to climate change. Under this proposed 4(d) rule, certain prohibitions and provisions that apply to endangered wildlife under the Act's section 9(a)(1) prohibitions would help minimize threats that could cause further declines in the species' status. The provisions of this proposed 4(d) rule would promote conservation of emperor penguins by ensuring that activities undertaken with the species by any person under the jurisdiction of the United States are also supportive of the conservation efforts undertaken for the species in Antarctica. The provisions of this proposed rule are one of many tools that we would use to promote the conservation of emperor penguins. This proposed 4(d) rule would apply only if and when we make final the proposed listing of the emperor penguin as a threatened species.

Provisions of the Proposed 4(d) Rule

In the SSA report and this proposed rule, we identified the factor of climate change as the greatest threat to the species. However, other activities of tourism, research, commercial krill fisheries, and activities that could lead to marine pollution also may affect emperor penguins. Except for climate change, these other factors all have minor effects on emperor penguins. Although this proposed 4(d) rule addresses the threats that have minor effects on emperor penguins, regulating these activities could help conserve emperor penguins and decrease synergistic, negative effects from the threat of climate change. Thus, the proposed 4(d) rule would provide for the conservation of the species by regulating and prohibiting the following activities, except as otherwise authorized or permitted: Importing or exporting; take; possession and other acts with unlawfully taken specimens; delivering, receiving, transporting, or shipping in interstate or foreign commerce in the course of commercial activity; or selling or offering for sale in interstate or foreign commerce. Under the Act, ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulations at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. Prohibiting take applies to take within the United States, within the territorial sea of the United States, or upon the high seas.

As noted previously, in the United States, the Antarctic Conservation Act of 1978 (ACA; 16 U.S.C. 2401 *et seq.*) provides for the conservation and protection of the fauna and flora of Antarctica, and of the ecosystem upon which such fauna and flora depend, consistent with the Antarctic Treaty and the Protocol. The ACA's implementing regulations (45 CFR part 670) include provisions relating to the conservation of Antarctic animals, including native birds such as emperor penguins. The National Science Foundation is the lead agency that manages the U.S. Antarctic Program and administers the ACA and its implementing regulations (45 CFR part 670).

Under the ACA, certain activities are prohibited related to flora and fauna in Antarctica. Of particular relevance to emperor penguins, the ACA prohibits take of any native bird within Antarctica without a permit. The term ''native bird'' under the ACA means any member, at any stage of its life cycle (including eggs), of any species of the class Aves which is indigenous to Antarctica or occurs there seasonally through natural migrations, and includes any part of such member (16 U.S.C. 2402(9); 45 CFR 670.3). Emperor

penguins are designated as native birds under the ACA (45 CFR 670.20). To ''take'' under the ACA means to kill, injure, capture, handle, or molest a native mammal or bird, or to remove or damage such quantities of native plants that their local distribution or abundance would be significantly affected or to attempt to engage in such conduct (16 U.S.C. 2402(20); 45 CFR 670.3). The ACA also makes it unlawful for any person, unless authorized by a permit, to receive, acquire, transport, offer for sale, sell, purchase, import, export, or have custody, control, or possession of, any native bird, native mammal, or native plant which the person knows, or in the exercise of due care should have known, was taken in violation of the ACA (16 U.S.C. 2403(b)(5)).

A permit system managed by the National Science Foundation, in coordination with appropriate agencies, issues permits under the ACA for certain, otherwise prohibited activities such as take, import, and export. Permits authorizing take of emperor penguins under the ACA may be issued only: (1) For the purpose of providing specimens for scientific study or scientific information; (2) for the purpose of providing specimens for museums, zoological gardens, or other educational or cultural institutions or uses; or (3) for unavoidable consequences of scientific activities or the construction and operation of scientific support facilities. Additionally, ACA permits shall ensure, as far as possible, that (1) no more native mammals, birds, or plants are taken than are necessary to meet the purposes set forth above; (2) no more native mammals or native birds are taken in any year than can normally be replaced by net natural reproduction in the following breeding season; (3) the variety of species and the balance of the natural ecological systems within Antarctica are maintained; and (4) the authorized taking, transporting, carrying, or shipping of any native mammal or bird is carried out in a humane manner (16 U.S.C. 2404(e); 45 CFR part 670, subparts C and D). Specific requirements also apply to permits for proposed imports and exports of emperor penguins (see 45 CFR part 670, subpart G). While we have found above that these current efforts alone will be inadequate to prevent the species from likely becoming in danger of extinction within the foreseeable future due to the unique nature of the threat of climate change, we also recognize the value these management efforts play in helping to conserve the species.

The ACA applies to the area south of 60 °S latitude, which encompasses Antarctica and the entire distribution of emperor penguins. Many provisions under the ACA are comparable to similar provisions in the Act, including with regard to take; prohibitions on activities with unlawfully taken specimens; and prohibitions on import and export. As discussed above, for decades, the ACA has provided significant conservation benefits and protections to the emperor penguin through its regulation of these activities with emperor penguin. Accordingly, we propose to provide exceptions from permitting requirements under the Act for certain otherwise prohibited activities with emperor penguins that are authorized by permit or regulation by the National Science Foundation under the ACA. Specifically, we propose to provide exceptions for take in Antarctica, import to the United States from Antarctica, and export from the United States to Antarctica when these activities are authorized under an ACA permit issued by the National Science Foundation. These exceptions would not apply where there is a violation of the ACA, and thus a violation of the ACA would also be a violation of the Act under the proposed 4(d) rule. For example, for import to the United States from Antarctica where the ACA requires an import permit, the import of an emperor penguin without an ACA permit would fail to meet the proposed regulatory exception, and therefore the import would be prohibited by both the ACA and the Act under the proposed 4(d) rule. A permit under the Act would be required for the import and export of any emperor penguins for any other purpose (*e.g.,* import from or export to another country, or import or export of a captive-bred emperor penguin). Accordingly, all imports and exports of emperor penguins would be prohibited unless authorized by an ACA permit, a permit under the Act, or for law enforcement purposes. Exceptions are also proposed to apply to take of emperor penguins, if the activity meets the ACA regulatory exceptions for emergency circumstances (45 CFR 670.5(a) and (c)), to aid or salvage a specimen (45 CFR 670.5(b) and (c)), or for law enforcement purposes (including the import or export of emperor penguins for law enforcement purposes; 45 CFR 670.9).

The proposed 4(d) rule also provides an exception for interstate commerce from public institutions to other public institutions, specifically museums, zoological parks, and scientific or educational institutions, meeting the definition of ''public'' at 50 CFR 10.12. The majority of records of import of emperor penguins into the United States have been for this very purpose. Demand for emperor penguins held at or captive-bred by these types of public institutions in the United States is not substantial nor is it likely to pose a significant threat to the wild population in Antarctica. As defined in our regulations, ''public'' museums, zoological parks, and scientific or educational institutions are those that are open to the general public and are either established, maintained, and operated as a governmental service or are privately endowed and organized but not operated for profit.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act. As noted above, we may also authorize certain activities associated with conservation breeding under CBW registrations. We recognize that captive breeding of wildlife can support conservation, for example by producing animals that could be used for reintroductions into Antarctica, if permitted under the ACA. We are not aware of any captive breeding programs for emperor penguins for this purpose. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act. This proposed 4(d) rule, if finalized, would apply to all live and dead emperor penguin parts and products, and support conservation management efforts for emperor penguins in the wild.

Required Determinations

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 proposed 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.

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 (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).

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 Branch of Delisting and Foreign Species (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Branch of Delisting and Foreign Species.

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. Amend § 17.11(h) by adding an entry for ''Penguin, emperor'' to the List of Endangered and Threatened Wildlife in alphabetical order under BIRDS to read as set forth below:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
BIRDS				
*	*	*	*	*
Penguin, emperor	*Aptenodytes forsteri*	Wherever found	T	[**Federal Register** citation when published as a final rule]; 50 CFR 17.41(k).[4d]
*	*	*	*	*

■ 3. Amend § 17.41 by adding a paragraph (k) to read as set forth below:

§ 17.41 Special rules—birds.

* * * * *

(k) Emperor penguin (*Aptenodytes forsteri*). (1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the emperor penguin. Except as provided under paragraph (k)(2) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

(i) Import or export, as set forth for endangered wildlife at § 17.21(b).

(ii) Take, as set forth for endangered wildlife at § 17.21(c)(1).

(iii) Possession and other acts with unlawfully taken specimens, as set forth for endangered wildlife at § 17.21(d)(1).

(iv) Interstate or foreign commerce in the course of commercial activity, as set forth for endangered wildlife at § 17.21(e).

(v) Sale or offer for sale in foreign commerce, as set forth for endangered wildlife at § 17.21(f).

(vi) Sale or offer for sale in interstate commerce, as set forth for endangered wildlife at § 17.21(f).

(2) *Exceptions from prohibitions.* In regard to the emperor penguin, you may:

(i) Sell, offer for sale, deliver, receive, carry, transport, or ship in interstate commerce live emperor penguins from one public institution to another public institution. For the purposes of this paragraph, ''public institution'' means a museum, zoological park, and scientific or educational institution that meets the definition of ''public'' at 50 CFR 10.12.

(ii) Take emperor penguins within Antarctica as authorized under implementing regulations for the Antarctic Conservation Act of 1978 (16 U.S.C. 2401 *et seq.*), either in accordance with the provisions set forth at 45 CFR 670.5 or 670.9, or as authorized by a permit under 45 CFR part 670.

(iii) Import emperor penguins into the United States from Antarctica or export emperor penguins from the United States to Antarctica as authorized under implementing regulations for the Antarctic Conservation Act of 1978 (16 U.S.C. 2401 *et seq.*), either in accordance with the provisions set forth at 45 CFR 670.9, or as authorized by a permit under 45 CFR part 670.

(iv) Conduct activities as authorized by a permit under § 17.32.

(v) Take, as set forth at § 17.21(c)(2) through (c)(4) for endangered wildlife.

(vi) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife.

(vii) Conduct activities as authorized by a captive-bred wildlife registration under § 17.21(g) for endangered wildlife.

* * * * *

Martha Williams,

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

[FR Doc. 2021–15949 Filed 8–3–21; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223

[RTID 0648–XB130]

Receipt of Receipt of a Petition To Issue Protective Regulations for Banggai Cardinalfish Under Endangered Species Act

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

ACTION: Receipt of petition for rulemaking; request for information.

SUMMARY: We, NMFS, announce receipt of a petition to promulgate a rulemaking under the Endangered Species Act (ESA) to provide for the conservation of the Banggai cardinalfish (*Pterapogon kauderni*). Specifically, the petition requests that we extend the prohibitions of the ESA to this species, including prohibitions on import, export, and all commercial activities for both wild and captive-bred populations. We solicit information and comments that may be relevant to our analysis of protective regulations.

DATES: Written comments and information must be received by October 4, 2021.

ADDRESSES: You may submit information on this document, identified by NOAA–NMFS–2021–0060, by the following method:

• *Electronic Submission:* Submit electronic information via the Federal e-Rulemaking Portal. Go to *www.regulations.gov* and enter NOAA–NMFS–2021–0060. Click on the ''Comment'' icon and complete the required fields. Enter or attach your comments.

Instructions: Comments sent by any other method or received after the end of the specified period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive or protected information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous submissions (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe portable electronic file (PDF) formats only.

The petition and previous rulemaking documents related to the listing of the species can be obtained electronically on the NMFS website at: *https://www.fisheries.noaa.gov/species/banggai-cardinalfish#conservation-management.*

FOR FURTHER INFORMATION CONTACT: Stephania Bolden by phone at (727 551–5768) or email at *Stephania.Bolden@noaa.gov;* or Erin Markin by phone at (301 427–8416) or email at *Erin.Markin@noaa.gov*, NMFS, Office of Protected Resources.

SUPPLEMENTARY INFORMATION:

Background

Section 4(d) of the ESA provides that, whenever a species is listed as threatened, the Secretary of Commerce (Secretary) shall issue such regulations as the Secretary deems necessary and advisable to provide for the conservation of the species (16 U.S.C. 1533(d)). Under section 4(d), the Secretary may by regulation extend to any threatened species any or all of the prohibitions in ESA section 9(a)(1), which apply automatically to fish or wildlife species listed as endangered (16 U.S.C. 1538(a)(1)). Section 9(a)(1) makes it unlawful, with limited specified exceptions, for any person subject to the jurisdiction of the United States to: (A) Import any such species into, or export any such species from the United States; (B) take any such species within the United States or the territorial sea of the United States; (C) take any such species upon the high seas; (D) possess, sell, deliver, carry, transport, or ship, by any means whatsoever, any such species taken in violation of subparagraphs (B) and (C); (E) deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of a commercial activity, any such species; (F) sell or offer for sale in interstate or foreign commerce any such species; or (G) violate any regulation pertaining to such species or to any threatened species of fish or wildlife listed pursuant to section 4 of the ESA and promulgated by the Secretary pursuant to authority provided by the ESA.

On January 20, 2016, we published a final rule listing Banggai cardinalfish as threatened under the ESA (81 FR 3023). The final listing rule provides a summary of our conclusions regarding the threats to the species, and the 2015 status review summarized the scientific information that informed the listing decision. These documents are available on the NMFS website (see **ADDRESSES**).

On March 29, 2021, we published a notice announcing the initiation of a 5-year review of the Banggai cardinalfish and requested information on the species, particularly information on the status, threats, and recovery of the species that has become available since its listing (86 FR 16326). On the basis of this review, as required under section 4(c)(2)(B) of the ESA, we will determine whether the listing classification for this species remains accurate, or whether the species should be reclassified (from threatened to endangered) or delisted (16 U.S.C. 1533(c)(2)(B)).

Information in the Petition

On April 22, 2021, we received a petition from the Center for Biological Diversity, Animal Welfare Institute, and the Defenders of Wildlife requesting we promulgate a rulemaking under section 4(d) of the ESA to provide for the conservation of the Banggai cardinalfish. The petition states that the Banggai cardinalfish are particularly vulnerable to extinction from collection for the aquarium trade, and that since the species' listing in 2016, populations have continued to decline, with collection from the wild still occurring to supply the aquarium trade. The petition also alleges the ecosystem the Banggai cardinalfish depend on is becoming unsuitable due to loss of key microhabitat species (corals, sea urchins, and sea anemones), coral bleaching events, and climate change. The petition states that between the loss of habitat and ''the decrease in the species' population abundance and fitness resulting from decades of overexploitation, Banggai cardinalfish cannot withstand continued, high levels of take from the wild.'' The petition concludes that an ESA section 4(d) rule is both ''necessary and advisable'' for the conservation of the species, and requests that we initiate rulemaking, specifically recommending we apply the prohibitions under ESA sections 9(a)(1)(A) and 9(a)(1)(E) through 9(a)(1)(G) (see Background) and require a threatened species permit for import or export of specimens, products, and live Banggai cardinalfish, including for introduced populations and captive-bred fish unless accompanied by a pre-Act Certificate of Exemption (50 CFR 222.201–222.205). The petition is available on the NMFS website (see **ADDRESSES**).

Information Solicited

NMFS will consider public comments and information received in evaluating the request by the petitioners (see **DATES** and **ADDRESSES**). In addition to comments and information pertaining to any aspect of the petition, NMFS

specifically requests information regarding:

- The adequacy of existing measures regulating collection and trade of the Banggai cardinalfish throughout its range;
- Availability and efficacy of captive-bred fish for aquaria trade both domestic and international;
- Information on the collection/harvest (including, but not limited to, number, location, mortality rate), and trade (import/export data, value, transit mortality rates) of wild fish for aquaria trade; and
- Implementation and efficacy of Indonesia's National Plan of Action (NPOA) (2017–2021) for Banggai cardinalfish and adequacy of enforcement of Banggai cardinalfish regulations.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2021–16220 Filed 8–3–21; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 86, No. 147

Wednesday, August 4, 2021

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.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2021–0030]

Notice of Request for an Extension of Approval of an Information Collection; Nomination Request Form; Animal Disease Training

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with training related to animal diseases.

DATES: We will consider all comments that we receive on or before October 4, 2021.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2021–0030 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2021–0030, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on training related to animal diseases, contact Ms. Alicia D. Love, Program Specialist, Professional People Training, Resources, People, and Service, Veterinary Services, APHIS, 4700 River Road, Unit 27, Riverdale, MD 20737; (301) 851–3425. For more information on the information collection reporting process, contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483; *joseph.moxey@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Nomination Request Form; Animal Disease Training.

OMB Control Number: 0579–0353.

Type of Request: Extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture is authorized, among other things, to protect the health of U.S. livestock and poultry populations by preventing the introduction and interstate spread of serious diseases and pests of livestock and by eradicating such diseases from the United States when feasible. In connection with this mission, APHIS' Veterinary Services (VS) program provides vital animal disease training.

VS Professional People Training provides training on responses to animal disease events, sample collection procedures, and disease mitigation and eradication activities to private veterinarians and State, Tribal, military, international, industry, and university personnel. The courses are designed to prepare participants for activities dealing with a U.S. animal disease incident. Individuals who wish to attend animal disease-related training must submit a Nomination Request Form (VS Form 1–5) to VS to help the program coordinate courses and select participants. VS develops rosters with course participants' names and contact information to notify them of future training courses and to encourage contact among participants throughout their careers.

We are asking the Office of Management and Budget (OMB) to approve our use of this information collection activity for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate 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) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.33 hours per response.

Respondents: State, Tribal, military, international, industry, and university personnel.

Estimated annual number of respondents: 350.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 350.

Estimated total annual burden on respondents: 116 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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

Done in Washington, DC, this 23rd day of July 2021.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–16632 Filed 8–3–21; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Fourth Access, Participation, Eligibility, and Certification Study Series (APEC IV)

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

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a Reinstatement, with change, of a previously approved collection for which approval has expired (OMB Number 0584–0530, Discontinued: 10/31/2020); for the Fourth Access, Participation, Eligibility, and Certification Study Series (APEC IV).

DATES: Written comments must be received on or before October 4, 2021.

ADDRESSES: Comments may be sent to: Amy Rosenthal, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 5th floor, Alexandria, VA 22314. Comments may also be via email to Amy Rosenthal at *amy.rosenthal@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Amy Rosenthal at *amy.rosenthal@usda.gov,* 703–305–2245.

SUPPLEMENTARY INFORMATION: *Comments are invited on:* (a) 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; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Fourth Access, Participation, Eligibility, and Certification Study Series (APEC IV).

Form Number: Not applicable.

OMB Number: 0584–0530.

Expiration Date: Not Yet Determined.

Type of Request: Reinstatement, with change, of a previously approved collection for which approval has expired.

Abstract:

USDA's Food and Nutrition Service (FNS) depends upon the APEC study series to provide reliable, national estimates of errors and improper payments made to school districts in which the National School Lunch Program and School Breakfast Program are operated. This is the fourth study in the APEC series and it will provide the required information for school year (SY) 2023–2024.

Program errors fall into three broad categories: Certification (determining the eligibility of a student for a given level of reimbursement), aggregation (adding up all the meal counts by reimbursement category as they are transmitted through the claims process), and meal claiming (ensuring that meals claimed meet the meal pattern requirements). Certification and aggregation errors contribute to improper payments, while meal claiming error is an operational error that does not result in an improper payment. The majority of improper payments in the programs result from certification errors, while aggregation errors are relatively rare.

The Payment Integrity Information Act of 2019 (PIIA) requires that FNS identify and reduce improper payments in these programs, including both underpayments and overpayments. In order to comply with the law, programs must have a statistically valid rate of improper payment below 10 percent, and programs out of compliance with PIIA are subject to increased scrutiny and reporting requirements.

Beyond statutory improper payment reporting requirements, FNS recognizes the human and economic costs of program error. For example, certification error may result in children being certified at a lower or higher level than the one for which they qualify; aggregation error may cause school districts to receive a lower or higher reimbursement than they should have received; and meal claiming error may result in a participant receiving a less balanced and nutritious meal than they would have if the meal pattern was followed.

Although the APEC II and the forthcoming APEC III findings show substantial improvement in certain types of error since APEC I, there is an ongoing need to identify and correct sources of program error.

The specific study objectives of APEC IV are:

- Objective 1: Generate a national estimate of the annual amount of improper payments in the National School Lunch Program and School Breakfast Program based on SY 2023–2024 by replicating and refining the methodology used in prior APEC studies.
- Objective 2: Provide a robust examination of the relationship between error rates and student (household), school, and school food authority (SFA) characteristics.
- Objective 3: Conduct two sub-studies testing the effect that data collection methods have on responses.
  - Electronic Application Sub-study: Evaluate whether USDA's online application prototype with integrity features generates a more accurate and complete accounting of household size and income compared to other online application types and paper applications.
  - Mode Effect Sub-Study: Assess the effect of in-person versus telephone interviews on responses to the household survey.

Consistent with methodology used in the previous studies in the APEC series, we will collect data to address the study objectives using a multistage–clustered sample design, which will include:

- A nationally representative sample of SFAs in the contiguous 48 states and the District of Columbia;
- A stratified sample of schools within each SFA; and
- A random sample of students (households) within each sampled school that applied for free and reduced-price meals, were categorically eligible for free meals, or were directly certified for free meals.

APEC IV will collect data to measure certification, aggregation, and meal claiming errors via in-person visits to SFAs and schools and surveys of SFA directors and households. Data collection will include (a) abstraction from income eligibility applications and categorical eligibility records; (b) abstraction of meal count and claiming records from SFAs, schools, States, and FNS administrative data; (c) an online survey of SFA directors; (d) meal observations in schools; and (e) a telephone survey of households.

The analysis plan includes the following components: (a) Calculating error rates; (b) estimating improper payments; (c) comparisons to previous APEC estimates (APEC I, II, III); and (d) quantitative analyses to identify factors associated with errors. The calculation of estimates from APEC IV will include the incidence of error, the total dollar amount of error, and the dollar based error rate. The comparisons to prior APEC studies will include tests for significant changes over time. The quantitative analyses will examine the sources and causes of errors with a focus on identifying strategies for reducing errors.

Affected Public: Individuals/Households and State, Local, or Tribal Governments. Respondent groups identified include: (1) Child Nutrition State agencies, (2) SFAs, (3) schools, and (4) parents/guardians of sampled students that are either certified to receive a free or reduced price meal or who applied for but were denied benefits in SY 2023–24.

Estimated Number of Respondents: The estimated number of respondents is 13,068. This includes 5,210 responses and 7,858 non-responses. The number of unique respondents expected to provide data for this study are 4,112 households and 1,098 State and Local Governments (44 State Agencies, 295 SFAs, and 759 schools).

Estimated Number of Responses per Respondent: All respondents will be asked to respond to each specific data collection activity only once. The overall average number of responses per respondent across the entire collection is 5.14.

Estimated Total Annual Responses: The estimated number of total annual responses is 67,317.

Estimated Time per Response: The estimated time of response varies from 1 minute to 4 hours depending on the respondent group, as shown in the burden table below. The estimated time per response is 11.49 minutes (0.191 hours).

Estimated Total Annual Burden on Respondents: 12,851.4 hours. This includes 12,419.6 hours for respondents and 431.7 hours for non-respondents. See the table below for estimated total annual burden for each type of respondent.

BILLING CODE 3410–30–P

Burden Table:

				Responsive					Non-Responsive					
Respondent Category	Type of respondents	Instruments	Sample Size	Number of respondents	Frequency of response	Total Annual responses	Hours per response	Annual burden (hours)	Number of Non-respondents	Frequency of response	Total Annual responses	Hours per response	Annual burden (hours)	Grand Total Annual Burden Estimate (hours)
Individuals/ Households	Pretest	Household Survey, including income documentation mode	9	9	1	9	0.75	6.8	0	1	0	0.0167	0.0	6.8
	Program Participants	Household Survey Recruitment Guide - Telephone Survey	11,723	4,103	1	4,103	0.0835	342.6	7620	1	7,620	0.0167	127.3	469.9
		Household Survey Brochure	11,723	4,103	1	4,103	0.0835	342.6	7620	1	7,620	0.0167	127.3	469.9
		Household Survey Recruitment Guide - Telephone Survey	5,471	4,103	1	4,103	0.167	685.2	1368	1	1,368	0.0501	68.5	753.7
		Household Confirmation and Reminder of Telephone Survey	4,103	4,103	1	4,103	0.05	205.6	0	1	0	0.0167	0.0	205.6
		Household Survey Recruitment Guide - In-Person Survey	375	300	1	300	0.167	50.1	75	1	75	0.0501	3.8	53.9
		Household Fact Sheet Re In-Person Survey	375	300	1	300	0.0334	10.0	75	1	75	0.0167	1.3	11.3
		Household Confirmation of In-Person Survey	375	300	1	300	0.05	15.0	75	1	75	0.0167	1.3	16.3
		Household recruitment website	5,471	1,641	1	1,641	0.4342	712.7	3830	1	3,830	0.0	0.0	712.7
		Household Survey Income Worksheet	5,471	4,103	1	4,103	0.334	1,370.4	1368	1	1,368	0.0167	22.8	1,393.2
		Downloading video call software for income verification	2,052	1,846	1	1,846	0.25	462.5	205.15	1	205	0.0	0.0	462.5
		Household Survey	5,471	4,103	1	4,103	0.75	3,083.4	1368	1	1,368	0.0167	22.8	3,106.3
Individuals/ Households Sub-Total			11,732	4,112	7.06	29,015	0.2511	7,286.8	7,620	3.10	23,604	0.016	375.0	7661.84
State Child Nutrition Agency	State Director	Official Study Notification from FNS Regional Liaisons to State CN Director, including sending study notification to SFAs	44	44	1	44	0.5	22.0	0	1	0	0.0167	0.0	22.0
		Unstructured qualitative interview	44	44	1	44	0.5	22.0	0	1	0	0.0167	0.0	22.0
		State Director Recruitment Website	44	44	1	44	0.5511	24.2	0	1	0	0.0167	0.0	24.2
	Data Manager	State Meal Claim Data Request	44	44	1	44	4.00	176.0	0	1	0	0.0167	0.0	176.0
SFA	SFA Director	SFA pretest	9	9	1	9	0.75	6.8	0		0	0.0167	0.0	6.8

		SFA Study Notification Template from State CN Director	336	286	1	286	0.0334	9.6	50	1	50	0.0334	1.7	11.2
		SFA Study Notification and Data Request + School Data Verification Reference Guide	336	286	1	286	3.00	858.0	50	1	50	0.5	25.0	883.0
		SFA Follow Up Discussion Guide (Study Notification and School Data Verification)	336	286	1	286	0.25	71.6	50	1	50	0.25	12.5	84.1
		Automated Email to Confirm Receipt of School Data	286	286	1	286	0.0167	4.8	0	1	0	0.0167	0.0	4.8
		SFA Confirmation and Next Steps Email	286	286	1	286	0.05	14.3	0	1	0	0.0167	0.0	14.3
		SFA School Sample Notification Email, including sending study notification to schools (using the Study Notification Template)	286	286	1	286	0.334	95.5	0	1	0	0.0167	0.0	95.5
		SFA Follow-Up Discussion Guide (School Sample Notification)	286	286	1	286	0.25	71.6	0	1	0	0.0167	0.0	71.6
		APEC IV Fact Sheet (for SFAs and Schools)	336	302	1	302	0.0835	25.3	33.6	1	34	0.0167	0.6	25.8
		SFA Director Recruitment Website	286	257	1	257	0.8016	206.3	28.6	1	29	0.0167	0.5	206.8
	SFA Staff	SFA Request and Reminder for E-Records (CEP Schools for ISP Data Abstraction)	213	181	1	181	0.5	90.7	32	1	32	0.0167	0.5	91.2
		SFA Request and Reminder for E-Records_Part A Prior SY (Non CEP Schools for Household Sampling)	123	105	1	105	1.00	105.0	18	1	18	0.0167	0.3	105.3
		SFA Request and Reminder for E-Records_Part B Current SY (Non-CEP Schools for Household Sampling)	105	105	1	105	1.00	105.0	0	1	0	0.0167	0.0	105.0
		Application Data Abstraction Form	105	105	1	105	1.00	105.0	0	1	0	0.0167	0.0	105.0
		SFA Initial Visit Contact Email with SFA and School Pre-Visit Interviews	286	286	1	286	0.334	95.5	0	1	0	0.0167	0.0	95.5
		SFA Data Collection Visit Confirmation Email	286	286	1	286	0.0835	23.9	0	1	0	0.0167	0.0	23.9
		SFA Data Collection Reminder Email	286	286	1	286	0.0835	23.9	0	1	0	0.0167	0.0	23.9
		SFA Director Web Survey	286	286	1	286	0.5	143.3	0	1	0	0.0167	0.0	143.3
	Data Manager	SFA Meal Participation Data Request	286	286	1	286	2.00	572	0	1	0	0.0167	0.0	572
		SFA Meal Claim Reimbursement Verification Form_Sampled Schools	286	286	1	286	0.5	143.3	0	1	0	0.0167	0.0	143.3
		SFA Reimbursement Consolidation and Verification Form_all schools	286	286	1	286	0.5	143.3	0	1	0	0.0167	0.0	143.3

Schools	School Principal	Email notification from SFA	938	750	1	750	0.0334	25.1	188	1	188	0.0167	3.1	28.2
		School Study Notification Letter	938	750	1	750	0.0835	62.6	188	1	188	0.0167	3.1	65.8
		School Follow Up Discussion Guide	938	750	1	750	0.334	250.5	188	1	188	0.0167	3.1	253.6
		School Confirmation Email	750	750	1	750	0.0835	62.6	0	1	0	0.0167	0.0	62.6
		School Notification of Household Data Collection	750	750	1	750	0.0835	62.6	0	1	0	0.0167	0.0	62.6
		APEC IV Fact Sheet (for SFAs and Schools)	938	750	1	750	0.1336	100.2	0	1	0	0.0167	0.0	100.2
	Cafeteria Manager	Meal Observation Pilot (Dual Camera and Paper Booklet Observations)[j]	9	9	1	9	1.50	13.5	0	1	0	0.0167	0.0	13.5
		School Data Collection Visit Confirmation Email	750	750	1	750	0.0334	25.1	0	1	0	0.0167	0.0	25.1
		School Data Collection Visit Reminder Email, including menu request	750	750	1	750	0.5	375.8	0	1	0	0.0167	0.0	375.8
		Paper Meal Observation Form/Camera protocol for meal observations	750	750	1	750	0.5	375.8	0	1	0	0.0167	0.0	375.8
		School Recruitment Website	938	563	1	563	0.4342	244.4	375	1	375	0.0167	6.3	250.6
		School Meal Count Verification Form	750	750	1	750	0.5	375.8	0	1	0	0.0167	0.0	375.8
State/Local/Tribal Government Sub-Total			1,336	1,098	12.13	13,317	0.3854	5,132.8	238	5.05	1,201	0.047	56.7	5,189.52
	TOTAL		**13,068**	**5,210**	**8.13**	**42,331**	**0.2934**	**12,419.6**	**7,858**	**3.16**	**24,805**	**0.017**	**431.7**	**12,851**

Timothy English,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2021–16642 Filed 8–3–21; 8:45 am]

BILLING CODE 3410–30–C

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Request for Information: Buy American in the National School Lunch Program and School Breakfast Program

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

ACTION: Notice: Request for information.

SUMMARY: This is a Request for Information from stakeholders, including local operators, State administrators, industry and producers, about the Buy American provision in the National School Lunch Program (NSLP) and the School Breakfast Program (SBP). The NSLP and SBP, which are administered by the United States Department of Agriculture (USDA) Food and Nutrition Service (FNS), play a critical role in ensuring that America's children have access to nutritious food they need to learn and succeed in the classroom, in addition to supporting American agriculture, and small, minority, and women's businesses and agricultural producers. In order to claim Federal reimbursement for meals served, school food authorities (SFAs) must follow Federal procurement and program regulations. These include the Buy American provision. The purpose of this Request for Information is to help FNS gather feedback from a wide variety of stakeholders on how the Buy American provision and guidance are currently implemented, changes FNS should make to current regulations and guidance and feedback on how FNS can better support local operators as they strive to purchase domestic foods and food products.

DATES: Written comments must be received on or before November 2, 2021.

ADDRESSES: USDA invites the submission of the requested information through one of the following methods:

- *Federal eRulemaking Portal (preferred method):* Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Mail:* Send written comments to the School Meals Monitoring Branch, Program Monitoring and Operational Support Division, Child Nutrition Programs, USDA Food and Nutrition Service, Braddock Metro Center II, 1320 Braddock Place, Alexandria, VA 22314.

All comments submitted in response to this Request for Information will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. USDA will make the comments publicly available via *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Jessica Saracino, School Meals Monitoring Branch, Program Monitoring and Operational Support Division, Child Nutrition Programs, USDA Food and Nutrition Service, 703–605–3223.

SUPPLEMENTARY INFORMATION: On January 25, 2021, President Biden signed the *Executive Order on Ensuring the Future is Made in All of America by All of America's Workers* (referred to as the Buy American Executive order hereafter) supporting the American economy by requiring terms and conditions of Federal financial assistance awards and Federal procurements to maximize the use of goods, products, and materials produced in, and services offered in, the United States. FNS is issuing this RFI in response to this Executive Order.

Section 104(d) of the William F. Goodling Child Nutrition Reauthorization Act of 1998 (Pub. L. 105–336) added a provision, Section 12(n) to the National School Lunch Act (NSLA) (42 U.S.C. 1760(n)), requiring school food authorities (SFAs) to purchase, to the maximum extent practicable, domestic commodities or products. This Buy American provision supports the mission of the Child Nutrition Programs, which is to serve children nutritious meals and support American agriculture. The existing regulatory provision stems directly from the statutory requirement.

The Buy American provision applies to SFAs located in the 48 contiguous United States and is one of the procurement standards these SFAs must comply with when purchasing commercial food and food products served in NSLP and SBP. Although Alaska, Hawaii, and the U.S. territories are exempt from the Buy American provision, SFAs in Hawaii are required to purchase food and food products produced in Hawaii in sufficient quantities, as determined by the SFA, to meet NSLP and SBP needs per 7 CFR 210.21(d)(3) and 7 CFR 220.16(d)(3). Likewise, SFAs in Puerto Rico are required to purchase food and food products produced in Puerto Rico in sufficient quantities, under 42 U.S.C. 1760(n)(4).

Section 12(n) of the NSLA defines ''domestic commodity or product'' as an agricultural commodity that is produced in the United States and a food product that is processed in the United States substantially using agricultural commodities produced in the United States. Report language accompanying the legislation noted that ''substantially means over 51% from American products.'' Accordingly, FNS has established in guidance that over 51% of the final processed product must consist of agricultural commodities that were grown domestically. Thus, for foods that are unprocessed, agricultural commodities must be domestic, and for foods that are processed, they must be processed domestically using domestic agricultural food components that are comprised of over 51% domestically grown items, as determined by the SFA. Any processed product used must contain over 51% of the product's food component from United States origin. This definition of domestic product serves both the needs of schools and American agriculture. Foods and food products from Guam, American Samoa, Virgin Islands, Puerto Rico, and the Northern Mariana Islands are considered domestic products under this provision as these products are from the territories of the United States.

FNS has provided through guidance limited exceptions to the Buy American provision which allow for the purchase of foods not meeting the ''domestic'' standard as described above (*i.e.,* ''non-domestic'') in circumstances when use of domestic foods is truly not practicable. These exceptions, as determined by the SFA, are:

- The product is not produced or manufactured in the United States in sufficient and reasonably available quantities of a satisfactory quality; or
- Competitive bids reveal the costs of a United States product are significantly higher than the non-domestic product.

It should be noted that FNS has not defined a dollar amount or percentage triggering possible use of an exception. It is each individual SFA's responsibility to determine what dollar amount or percentage constitutes a significantly higher price thus permitting the use of the exception. If an SFA is using one of the above exceptions, there is no requirement at this time to request a waiver from the State agency or FNS in order to purchase a non-domestic product. SFAs must, however, keep documentation justifying their use of exception(s). State agencies must ensure SFA compliance with the Buy American provision when conducting oversight processes.

FNS has already received feedback that stakeholders face difficulties in implementing and monitoring the Buy American provision and guidance. Additionally, stakeholders have reached out for assistance with interpreting and following the Buy American provision and have also requested help with understanding the exceptions. Feedback provided in response to this Request for Information will help inform future rulemaking and guidance around the Buy American provision.

Maximizing the Value of Public Feedback

This notice contains a list of questions, the answers to which will assist FNS in identifying those regulations, and/or policies that may benefit from modification, streamlining, expansion, or repeal in light of the Buy American Executive order. FNS encourages public comment on these questions and seeks any other data commenters believe are relevant to FNS's review efforts. The type of feedback that is most useful to the agency includes feedback that identifies specific regulations and/or policies that could benefit from reform; feedback that refers to specific barriers to participation; feedback that offers actionable data; and feedback that specifies viable alternatives to existing approaches that meet statutory obligations. For example, feedback that simply states that a stakeholder feels strongly that FNS should change a regulation or policy but does not contain specific information on how the proposed change would impact the costs and benefits of the regulation, is much less useful to FNS. FNS is looking for new information and new data to support any proposed changes. Highlighted below are a few of those points, noting comments that are most useful to FNS. Commenters should consider these principles as they answer and respond to the questions in this notice.

- Commenters should identify, with specificity, the program regulation and/or policy at issue, providing the Code of Federal Regulation (CFR) citation where appropriate.
- Commenters should identify, with specificity, administrative burdens, program requirements, or unnecessary complexity that may impose unjustified barriers in general, or that may have adverse effects on equity for all, including individuals who belong to underserved communities that have been denied equitable treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities, including learning disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.
- Commenters should provide, in as much detail as possible, an explanation why a program regulation and/or policy should be modified, streamlined, expanded, or repealed, as well as specific suggestions of ways the agency can better achieve its statutory and regulatory objectives in light of the Buy American Executive order.
- Commenters should provide specific data that document the costs, burdens, and benefits of existing requirements to the extent they are available.

List of Questions for Commenters

This Request for Information reflects the commitment of FNS to work with our stakeholders, including local operators, State administrators, industry and producers, to ensure that the Program-specific Buy American provision support the Administration's priorities, is practicable and that FNS provides adequate guidance.

The below non-exhaustive list of questions is meant to assist members of the public in the formulation of comments and is not intended to restrict the issues that commenters may address.

General

1. What changes, if any, to the Buy American provision and guidance would you recommend to FNS to support the Buy American executive order? Please describe in detail.

2. Please describe what works well for your organization when implementing and/or meeting the Buy American provision.

3. Please describe any challenges or impediments identified in meeting or monitoring the Buy American provision.

4. Do you have State-specific requirements to ensure SFAs comply with the Buy American provision (*e.g.,* recording every exception used, listing alternatives considered, etc.)? If so, please describe in detail.

5. Does your SFA use geographic preference when soliciting for unprocessed locally grown or locally raised agricultural products?

a. If not, what are the reason(s) your SFA does not use geographic preference to purchase locally grown or locally raised agricultural products?

6. Does your SFA use small, minority, and/or women's businesses, including Tribal businesses, and labor surplus firms to purchase or process foods from local producers such as farmers, ranchers, and other producers, or to process unprocessed, locally grown agricultural commodities into usable food products, needed to operate the NSLP and SBP? If yes, which of the above does your SFA use and how often? Please describe whether your SFA has experienced any additional benefits (other than obtaining affordable foods) by using local producers.

7. Please provide suggestions on how FNS can support stakeholders in meeting the Buy American provision or in connecting U.S. food producers to local schools.

Exceptions

8. FNS allows two limited exceptions to the Buy American provision: Costs of a United States product that are significantly higher than the non-domestic product, and insufficient domestic quality or quantity. List the foods and/or food products that most often require an exception.

(a.) Exceptions due to quantity or quality

(b.) Exceptions due to a significantly higher cost

9. If these currently available exceptions were more or less available, what impacts would this have?

10. Do you think FNS should establish additional detail in the regulations for the Buy American provision?

11. Do you think FNS should define what is considered a significantly higher cost? If so, how should FNS define ''significant''? Please be as specific as possible.

12. What methodology do you use to determine a significantly higher cost to your SFA that will require the purchase of non-domestic foods or food products? Do you use a dollar value or percentage in your determination? If yes, list the dollar value or percentage you use.

13. Should FNS consider a defined list of Buy American ''excepted'' items for food or food products that have been determined as not produced in the United States in sufficient and reasonably available commercial quantities of a satisfactory quality? If so, what criteria would you use to include items on this list, and which items would currently be included?

Collection of Information Requirements: This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure

requirements. However, this document does contain a general solicitation of comments in the form of a request for information. In accordance with implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Timothy English,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2021–16479 Filed 8–3–21; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: WIC Nutrition Assessment and Tailoring Study—In-Person Data Collection

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

ACTION: 60-Day notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a revision of the currently approved collection for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Nutrition Assessment and Tailoring Study (WIC NATS) [OMB Control Number 0584–0663]. The revision adds data collection from in-person site visits, where the data collection activities planned for the currently approved remote site visits will be replicated for use with 30 WIC clinic sites for in-person site visits once WIC clinic sites safely resume in-person operations.

DATES: Written comments must be received on or before October 4, 2021.

ADDRESSES: Comments may be sent to: Alexander Bush, Office of Policy Support, Food and Nutrition Service, USDA, 1320 Braddock Place, Alexandria, VA 22314. Comments may also be submitted via fax to the attention of Karen Castellanos-Brown at 703–305–2732 or via email to *Karen.Castellanos-Brown@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information on or copies of this information collection should be directed to Karen Castellanos-Brown at *Karen.Castellanos-Brown@usda.gov* or Courtney Paolicelli at 571–302–6447.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) 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; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: WIC Nutrition Assessment and Tailoring Study: In-Person Data Collection.

Form Number: Not applicable.

OMB Number: 0584–0663.

Expiration Date: 04/30/2024.

Type of Request: Revision of a currently approved collection.

Abstract: The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) provides supplemental foods, nutrition education and breastfeeding support, and referrals to health care and other social services to safeguard the health of low-income women, infants, and children up to 5 years of age who are at nutritional risk. As part of the certification and recertification process, WIC staff perform a comprehensive nutrition risk assessment with each participant to screen for certain nutrition risks and collect other relevant dietary and health information. Based on the nutrition risk assessment, WIC staff can individualize the food package benefits, nutrition education, and referrals the participant receives to meet their unique nutritional needs. While guidelines for conducting a quality nutrition risk assessment are described in the Value Enhanced Nutrition Assessment (VENA) guidance,[1] there is flexibility in how WIC staff conduct the nutrition risk assessment, and specifics of the process may vary by WIC State Agency (SA) and by WIC Local Agency (LA). Through this study, FNS seeks to better understand the nutrition services process as it transpires at WIC clinics, and WIC staff and participants' satisfaction with the process. The findings from this study will be used to develop guidance for WIC staff to enhance service delivery to improve program satisfaction, retention, and participant health and nutrition outcomes.

The four study objectives are: (1) Provide in-depth descriptive information on how a large, diverse sample of local WIC agencies performs the WIC nutrition risk assessment; (2) Systematically describe how a national sample of diverse local WIC agencies uses the collection of nutrition risk assessment information to tailor program benefits, including food packages, nutrition education, breastfeeding promotion and support, and referrals to health and social services; (3) Investigate relationships between WIC nutrition risk services processes (to include the nutrition risk assessment and the associated tailoring of program benefits), and the clinic experience, participant and staff perceptions, and overall clinic flow and efficiency; and (4) Identify specific practices or features of nutrition risk service processes that facilitate the use of nutrition assessment information for providing tailored program benefits, and that are associated with participant and staff satisfaction.

Under the currently approved WIC NATS data collection [OMB Control Number 0584–0663], 30 clinic sites will be selected to participate in remote site visits—where the study team will observe remote nutrition assessment visits (*i.e.,* assessments done via telephone or video call) and then interview WIC participants and staff by telephone. Under this revision, 30 clinic sites will be recruited to participate in the same data collection activities—including direct observation of nutrition assessments and interviews with

[1] U.S. Department of Agriculture Food and Nutrition Service. *VENA Value Enhanced Nutrition Assessment.* Available at: *https://wicworks.fns.usda.gov/resources/value-enhanced-nutrition-assessment-vena-guidance.*

participants and staff—during in-person site visits. Information collected under this revision will be used to better understand how the nutrition risk assessment process is conducted in a typical, face-to-face setting. This information will also be compared to similar information collected during the remote site visits.

This phase of data collection for in-person site visits reduces the burden to the information collection. While the Local Agencies participated in the remote data collection, the collection activities for the in-person site visits do not collect information from them. As a result, they have been removed from the collection. Although the data collection from the in-person site visits actually adds burden to the four currently approved elements of the collection: (1) Direct observation of nutrition assessments, (2) interviews with clinic site directors; (3) interviews with clinic staff, and (4) interviews with WIC participants, this increase is offset by the removal of the Local Agencies from this collection. Estimates of the number of respondents and hours associated with this data collection are given below. The content of the currently approved data collection instruments has not changed.

Affected Public: (1) State, Local, and Tribal Government; (2) Business or Other for Profit; (3), Not For Profit Organizations; and (4) Individuals/Households. Respondent groups identified include: (1) State, local, and tribal governments (WIC clinic sites); (2) Businesses/Non-Profits; (WIC clinic sites); and (3) Individuals (adults who participate in WIC or who have children that participate in WIC).

Estimated Number of Respondents: The total estimated number of respondents is 1,050 (540 respondents and 510 non-respondents). The total includes 30 clinics (21 government and 9 business), and 1,020 individuals.

Estimated Number of Responses per Respondent: The estimated frequency of response across the entire collection is 4.63. The estimated frequency of response is 5.78 annually for respondents and 3.42 annually for non-respondents. For most of the items in the collection, respondents reply to them only once, with the exception of the informed consents for the observation and staff interviews, the identified risks data collection form, and the staff interview guide. The WIC Clinic respondents will provide consent six times and will complete the data collection form and the interview five times.

Estimated Total Annual Responses: The estimated total number of annual responses is 4,865 (3,120 respondents and 1,745 non-respondents).

Estimated Time per Response: The estimated average response time per response across all respondents in the collection is 0.10 hours (0.15 hours for responsive participants and 0.02 hours for nonresponsive participants). The estimated time of response varies from one minute (0.02 hours) to one hour depending on the respondent group and activity, as shown in table 1.

Estimated Total Annual Burden on Respondents: The total public reporting burden for this collection of information is estimated at 509.38 hours (annually). See table 1 for estimated total annual burden for each type of respondent.

Timothy English,

Acting Administrator, Food and Nutrition Service.

BILLING CODE 3410–30–P

Table 1. Total Public Burden Hours

				Responsive					Non-responsive					
Respondent Category	**Type of respondents**	**Instruments**	**Sample Size**	**Number of respondents**	**Frequency of response (annual)**	**Total Annual responses**	**Hours per response**	**Total Annual Burden (hours)**	**Number of Non-respondents**	**Frequency of response (annual)**	**Total Annual responses**	**Hours per response**	**Total Annual Burden (hours)**	**Grand Total Burden Estimate (hours)**
State, Local, or Tribal Government	**WIC Clinic**	Site Visit Email to WIC Clinic and Schedule Call	21	21	1	21	0.08	1.75	0	1	0	0.02	0.00	1.75
		Telephone Call with WIC Clinic	21	21	1	21	1.00	21.00	0	1	0	0.02	0.00	21.00
		Informed Consent for Site Director Interview	21	21	1	21	0.08	1.75	0	1	0	0.02	0.00	1.75
		Site Director Interview Guide	21	21	1	21	0.75	15.75	0	1	0	0.02	0.00	15.75
		Finalize Plans with WIC Clinic on Day of Site Visit	21	21	1	21	0.25	5.25	0	1	0	0.02	0.00	5.25
		Informed Consent for Observation and Staff Interview	21	21	6	126	0.08	10.52	0	6	0	0.02	0.00	10.52
		Identified Risks Data Collection Form	21	21	5	105	0.08	8.77	0	5	0	0.02	0.00	8.77
		Staff Interview Guide	21	21	5	105	1.00	105.00	0	5	0	0.02	0.00	105.00
TOTAL STATE, LOCAL, TRIBAL GOVT			**21**	**21**	**21.00**	**441**	**0.39**	**169.80**	**0**	**0.00**	**0**	**0.00**	**0.00**	**169.80**
Business or Other For-Profit and Nonprofit Institutions	**WIC Clinic**	Site Visit Email to WIC Clinic and Schedule Call	9	9	1	9	0.08	0.75	0	1	0	0.02	0.00	0.75
		Telephone Call with WIC Clinic	9	9	1	9	1.00	9.00	0	1	0	0.02	0.00	9.00
		Informed Consent for Site Director Interview	9	9	1	9	0.08	0.75	0	1	0	0.02	0.00	0.75
		Site Director Interview Guide	9	9	1	9	0.75	6.75	0	1	0	0.02	0.00	6.75
		Finalize Plans with WIC Clinic on Day of Site Visit	9	9	1	9	0.25	2.25	0	1	0	0.02	0.00	2.25
		Informed Consent for Observation and Staff Interview	9	9	6	54	0.08	4.51	0	6	0	0.02	0.00	4.51
		Identified Risks Data Collection Form	9	9	5	45	0.08	3.76	0	5	0	0.02	0.00	3.76
		Staff Interview Guide	9	9	5	45	1.00	45.00	0	5	0	0.02	0.00	45.00

TOTAL PROFIT/NON-PROFIT BUSINESS			**9**	**9**	**21.00**	**189**	**0.39**	**72.77**	**0**	**0.00**	**0**	**0.00**	**0.00**	**72.77**
Individuals and Households	**WIC Participants**	Study Brochure for WIC Participant	1,020	510	1	510	0.05	25.55	510	1	510	0.02	8.52	34.07
		WIC Participant Screener	1,020	510	1	510	0.02	8.52	510	1	510	0.02	8.52	17.03
		Informed Consent for Observation and WIC Participant Interview	510	510	1	510	0.08	42.59	0	1	0	0.02	0.00	42.59
		Nutrition Services Observation Form	510	510	1	510	0.02	8.52	0	1	0	0.02	0.00	8.52
		WIC Participant Interview Guide (In-Person)	510	150	1	150	0.50	75.00	360	1	360	0.02	6.01	81.01
		WIC Participant Interview Guide (Phone)	255	150	1	150	0.50	75.00	105	1	105	0.02	1.75	76.75
		Reminder Text for WIC Participant Interview to be Conducted Over the Phone	255	100	1	100	0.02	1.67	155	1	155	0.02	2.59	4.26
		Reminder Call for WIC Participant Interview to be Conducted Over the Phone	155	50	1	50	0.02	0.84	105	1	105	0.02	1.75	2.59
TOTAL OF WIC PARTICIPANTS			**1,020**	**510**	**4.88**	**2,490**	**0.10**	**237.68**	**510**	**3.42**	**1,745**	**0.02**	**29.14**	**266.82**
TOTAL REPORTING BURDEN			**1,050**	**540**	**5.78**	**3,120**	**0.15**	**480.24**	**510**	**3.42**	**1,745**	**0.02**	**29.14**	**509.38**

[FR Doc. 2021–16574 Filed 8–3–21; 8:45 am]

BILLING CODE 3410–30–C

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–824]

Polyethylene Terephthalate Film, Sheet, and Strip From India: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review; 2019–2020

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

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip (PET film) from India. The period of review (POR) is July 1, 2019, through June 30, 2020. This review covers Jindal Poly Films Ltd. (Jindal) and SRF Limited of India (SRF), producers and exporters of PET film from India. Commerce preliminarily determines that Jindal and SRF did not make sales of subject merchandise below normal value during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable August 4, 2021.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith at (202) 482–5255; AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2020, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on PET film from India, for the period July 1, 2019, through June 30, 2020.[1] Subsequently, on September 3, 2020, in accordance with 19 CFR 351.222(c)(1)(i), Commerce published a notice of initiation of an administrative review of the antidumping duty order on PET film from India.[2]

On March 30, 2021, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.213(h)(2), Commerce extended the due date for the preliminary results by 60 days (from April 2, 2021 to July 1, 2021).[3] On June 17, 2021, we extended the deadline by an additional 28 days.[4] The current deadline is July 29, 2021.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.*

Scope of the Order [5]

The products covered by this *Order* are all gauges of raw, pretreated, or primed polyethylene terephthalate film, sheet, and strip, whether extruded or coextruded. Excluded are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer of more than 0.00001 inches thick. Imports of PET film are classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item number 3920.62.00.90. HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of the *Order* is dispositive.

Partial Rescission of Administrative Review

Commerce initiated a review of eight separate companies in this proceeding.[6] We are rescinding this administrative review with respect to six of these companies: (1) Ester Industries Ltd. (Ester); (2) Garware Polyester Ltd. (Garware); (3) MTZ Polyesters Ltd. (MTZ); (4) Polyplex Corporation (Polyplex); (5) Uflex Ltd. (Uflex); and (6) Vacmet India Ltd. (Vacmet), pursuant to 19 CFR 351.213(d)(1), because all review requests of these companies were timely withdrawn. Accordingly, the companies that remain subject to the instant review are Jindal Poly Films Ltd. (Jindal) and SRF Limited of India (SRF).[7]

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Act. Export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following weighted-average dumping margins for the period July 1, 2019, through June 30, 2020.

Manufacturer/exporter	Weighted-average margin (percent)
Jindal Poly Films Ltd.	0.00
SRF Limited of India	0.00

Disclosure and Public Comment

We intend to disclose the calculations performed to parties in this proceeding within five days after public announcement of the preliminary results in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.[8] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief

[1] *See Antidumping or Countervailing Duty Order, Finding or Suspended Investigation; Opportunity to Request Administrative Review,* 85 FR 39531 (July 1, 2020).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 54983 September 3, 2020 (*Initiation Notice*).

[3] *See* Memorandum ''Polyethylene Terephthalate (PET) Film, Sheet and Strip from India: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review—2019–2020,'' dated March 30, 2021.

[4] *See* Memorandum ''Polyethylene Terephthalate (PET) Film, Sheet and Strip from India: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review—2019–2020,'' dated June 17, 2021.

[5] *See Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Film, Sheet and Strip from India,* 67 FR 44176 (July 1, 2002) (*Order*).

[6] *See Initiation Notice.* As noted above, SRF Ltd. is the same company as SRF Limited of India.

[7] SRF Limited and SRF Limited of India are the same company. *See* SRF's Letter, ''Polyethylene Terephthalate (PET) Film, Sheet and Strip from India/SRF Limited/Comments on U.S. Customs and Border Protection (CBP) Data Release,'' dated November 30, 2020. SRF states that ''{t}here is only one SRF producing the subject merchandise . . . SRF Limited.'' For purposes of this review, when we refer to SRF Limited, we will use the formal name, SRF Limited of India.

[8] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006, 17007 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications remain in effect)''); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

summary of the argument; and (3) a table of authorities.[9]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, must submit a written request to the Acting Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless extended, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon completion of this administrative review, Commerce shall determine, and U.S. CBP shall assess, antidumping duties on all appropriate entries. If a respondent's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates on the basis of the ratio of the total amount of dumping calculated for an importer's examined sales and the total entered value of those same sales, in accordance with 19 CFR 351.212(b)(1).[10] Where an importer-specific ad valorem assessment rate is zero or *de minimis* in the final results of the review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[11]

Commerce intends to issue assessment instructions to CBP 35 days after the date of publication of the final results of this administrative review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication.)

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of PET film from India entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the company under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters is 5.71 percent.[12] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: July 29, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Partial Rescission of Administrative Review
IV. Scope of the Order
V. Comparisons to Normal Value
VI. Date of Sale
VII. Export Price
VIII. Normal Value
IX. Currency Conversion
X. Recommendation

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[9] *See* 19 CFR 351.303 (for general filing requirements).

[10] Where Commerce has calculated export subsidies in a companion countervailing duty order administrative review, we have made an adjustment based on the most recently completed review. *See Polyethylene Terephthalate Film Sheet and Strip from India: Final Results of Countervailing Duty Administrative Review; 2017,* 85 FR 14463 (March 12, 2020).

[11] *See* 19 CFR 351.106(c)(2).

[12] *Order.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–557–822]

Utility Scale Wind Towers From Malaysia: Countervailing Duty Order

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

SUMMARY: Based on affirmative final determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC), Commerce is issuing the countervailing duty order on utility scale wind towers (wind towers) from Malaysia.

DATES: Applicable August 4, 2021.

FOR FURTHER INFORMATION CONTACT: Nathan James or Kelsie Hohenberger, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5305 and (202) 482–2517, respectively.

SUPPLEMENTARY INFORMATION:

Background

In accordance with section 705(d) of the Tariff Act of 1930, as amended (the Act), on June 9, 2021, Commerce published its affirmative final determination in the countervailing duty investigation of wind towers from Malaysia.[1] On July 26, 2021, the ITC notified Commerce of its affirmative final determination that an industry in the United States is materially injured within the meaning of section 705(b)(1)(A)(i) of the Act, by reason of subsidized imports of subject merchandise from Malaysia.[2]

Scope of the Order

The products covered by this order are wind towers from Malaysia. For a complete description of the scope of the order, *see* the appendix to this notice.

[1] *See Utility Scale Wind Towers from Malaysia: Final Affirmative Countervailing Duty Determination,* 86 FR 30593 (June 9, 2021).

[2] *See* ITC Letter, ''Notification of ITC Final Determinations,'' dated July 26, 2021.

Countervailing Duty Order

As noted above, on July 26, 2021, in accordance with section 705(d) of the Act, the ITC notified Commerce of its final determination in this investigation, in which it found that an industry in the United States is materially injured by reason of subsidized imports of wind towers from Malaysia.[3] Therefore, in accordance with section 705(c)(2) of the Act, Commerce is issuing this countervailing duty order. Because the ITC determined that imports of wind towers from Malaysia are materially injuring a U.S. industry, unliquidated entries of such merchandise from Malaysia, entered or withdrawn from warehouse for consumption, are subject to the assessment of countervailing duties.

In accordance with section 706(a) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, countervailing duties for all relevant entries of wind towers from Malaysia. With the exception of entries occurring after the expiration of the provisional measures period and before the publication of the ITC's final affirmative injury determination, as further described below, countervailing duties will be assessed on unliquidated entries of wind towers from Malaysia entered, or withdrawn from warehouse, for consumption on or after March 25, 2021, the date of publication of the *Preliminary Determination*.[4]

Suspension of Liquidation and Cash Deposits

In accordance with section 706 of the Act, Commerce will instruct CBP to reinstitute the suspension of liquidation of wind towers from Malaysia, as described in the appendix to this notice, effective on the date of publication of the ITC's final affirmative injury determination in the **Federal Register**, and to assess, upon further instruction by Commerce, pursuant to section 706(a)(1) of the Act, countervailing duties for each entry of the subject merchandise in an amount based on the net countervailable subsidy rates below. On or after the date of publication of the ITC's final injury determination in the **Federal Register**, CBP must require, at the same time as importers would deposit estimated normal customs duties on this merchandise, a cash deposit equal to the rates listed in the table below. The all-others rate applies to all producers or exporters not specifically listed, as appropriate.

Company	Subsidy rate (percent)
CS Wind Malaysia Sdn Bhd	6.42
All Others	6.42

Provisional Measures

Section 703(d) of the Act states that instructions issued pursuant to an affirmative preliminary determination may not remain in effect for more than four months. In the underlying investigation, Commerce published the *Preliminary Determination* on March 25, 2021. Therefore, the four-month period beginning on the date of the publication of the *Preliminary Determination* ended on July 22, 2021.

In accordance with section 703(d) of the Act, we will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to countervailing duties, unliquidated entries of wind towers from Malaysia entered, or withdrawn from warehouse, for consumption after July 22, 2021, the final day on which the provisional measures were in effect, until and through the day preceding the date of publication of the ITC's final injury determination in the **Federal Register**. Suspension of liquidation will resume on the date of publication of the ITC's final determination in the **Federal Register**.

Notification to Interested Parties

This notice constitutes the countervailing duty order with respect to wind towers from Malaysia pursuant to section 706(a) of the Act. Interested parties can find a list of countervailing duty orders currently in effect at *http://enforcement.trade.gov/stats/iastats1.html.*

This order is issued and published in accordance with section 706(a) of the Act and 19 CFR 351.211(b).

Dated: July 28, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Order

The merchandise covered by this order consists of certain wind towers, whether or not tapered, and sections thereof. Certain wind towers support the nacelle and rotor blades in a wind turbine with a minimum rated electrical power generation capacity in excess of 100 kilowatts and with a minimum height of 50 meters measured from the base of the tower to the bottom of the nacelle (*i.e.,* where the top of the tower and nacelle are joined) when fully assembled.

A wind tower section consists of, at a minimum, multiple steel plates rolled into cylindrical or conical shapes and welded together (or otherwise attached) to form a steel shell, regardless of coating, end-finish, painting, treatment, or method of manufacture, and with or without flanges, doors, or internal or external components (*e.g.,* flooring/decking, ladders, lifts, electrical buss boxes, electrical cabling, conduit, cable harness for nacelle generator, interior lighting, tool and storage lockers) attached to the wind tower section. Several wind tower sections are normally required to form a completed wind tower.

Wind towers and sections thereof are included within the scope whether or not they are joined with nonsubject merchandise, such as nacelles or rotor blades, and whether or not they have internal or external components attached to the subject merchandise.

Specifically excluded from the scope are nacelles and rotor blades, regardless of whether they are attached to the wind tower. Also excluded are any internal or external components which are not attached to the wind towers or sections thereof, unless those components are shipped with the tower sections.

Merchandise covered by this order is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheading 7308.20.0020 or 8502.31.0000. Wind towers of iron or steel are classified under HTSUS 7308.20.0020 when imported separately as a tower or tower section(s). Wind towers may be classified under HTSUS 8502.31.0000 when imported as combination goods with a wind turbine (*i.e.,* accompanying nacelles and/or rotor blades). While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

[FR Doc. 2021–16621 Filed 8–3–21; 8:45 am]

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[3] *Id.*

[4] *See Utility Scale Wind Towers from Malaysia: Preliminary Affirmative Countervailing Duty Determination,* 86 FR 15887 (March 25, 2021) (*Preliminary Determination*).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–891]

Carbon and Alloy Steel Wire Rod From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020

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

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that POSCO, a producer and exporter of carbon and alloy steel wire rod (wire rod) from the Republic of Korea (Korea), sold subject merchandise in the United States at prices below normal value during the period of review (POR) May 1, 2019, through April 30, 2020. We invite all interested parties to comment on these preliminary results.

DATES: Applicable August 4, 2021.

FOR FURTHER INFORMATION CONTACT: Lingjun Wang, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2316.

SUPPLEMENTARY INFORMATION:

Background

On May 21, 2018, Commerce published in the **Federal Register** the *Order.*[1] On April 8, 2019, Commerce revoked, in part, the *Order* with respect to grade 1078 and higher tire cord quality wire rod used in the production of tire cord wire.[2] On June 13, 2019, Commerce revoked, in part, the *Order* with respect to valve spring quality (VSQ) wire rod.[3]

Commerce is conducting this administrative review in accordance with section 751(a)(1)(B) of Tariff Act of 1930, as amended (the Act).[4] On July 10, 2020, in accordance with 19 CFR 351.221(c)(1)(i), we initiated this review covering POSCO, the sole producer and exporter for which a review was requested.[5]

On July 21, 2020, Commerce tolled all preliminary and final results in administrative reviews by 60 days.[6] On March 11, 2021 and June 17, 2021, we extended the deadline for issuing the preliminary results until July 30, 2021.[7]

For a detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[8]

Scope of the Order

The scope of the *Order* includes certain hot-rolled products of carbon steel and alloy steel, in coils, of approximately round cross section, less than 19.00 mm in actual solid cross-sectional diameter. Excluded from the scope are grade 1078 and higher tire cord quality wire rod to be used in the production of tire cord wire. Also, excluded from the scope are valve spring quality (VSQ) steel products which is defined as wire rod. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.[9]

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. Constructed export prices are calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Preliminary Results

We preliminarily determine the following weighted-average dumping margin for the period May 1, 2019, through April 30, 2020:

Exporter and producer	Weighted-average dumping margin (percent)
POSCO	7.51

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[10] The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review and for future deposits of estimated duties, where applicable.[11] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Pursuant to 19 CFR 351.212(b)(1), where an examined respondent's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent), we will calculate an importer-specific *ad valorem* duty assessment rate based on the ratio of the total amount of dumping calculated for the U.S. sales for a given importer to the total entered value of those sales. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For entries of subject merchandise during the POR produced by POSCO for which it did not know that its merchandise was destined for the United States, we will instruct CBP to liquidate such unreviewed entries pursuant to the reseller policy,[12] *i.e.,* the assessment rate for such entries will be equal to the all-others rate established in the investigation (*i.e.,* 41.10 percent), if there is no rate for the intermediate company(ies) involved in the transaction.

[1] *See Carbon and Alloy Steel Wire Rod from Italy, the Republic of Korea, Spain, the Republic of Turkey, and the United Kingdom: Antidumping Duty Orders and Amended Final Affirmative Antidumping Duty Determinations for Spain and the Republic of Turkey,* 83 FR 23417 (May 21, 2018) (*Order*).

[2] *See Carbon and Alloy Steel Wire Rod from the Republic of Korea and the United Kingdom: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 84 FR 13888 (April 8, 2019).

[3] *See Carbon and Alloy Steel Wire Rod from the Republic of Korea: Final Results of Antidumping Duty Changed Circumstances Review,* 84 FR 27582 (June 13, 2019).

[4] *See Carbon and Alloy Steel Wire Rod from Italy, the Republic of Korea, Spain, the Republic of Turkey, and the United Kingdom: Antidumping Duty Orders and Amended Final Affirmative Antidumping Duty Determinations for Spain and the Republic of Turkey,* 83 FR 23417 (May 21, 2018) (*Order*); *see also Carbon and Alloy Steel Wire Rod from the Republic of Korea and the United Kingdom: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 84 FR 13888 (April 8, 2019); and *Carbon and Alloy Steel Wire Rod from the Republic of Korea: Final Results of Antidumping Duty Changed Circumstances Review,* 84 FR 27582 (June 13, 2019).

[5] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 41540 (July 10, 2020).

[6] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020 (the deadline for the final results was actually tolled by 57 days because the tolling started three day before the publication date of the *Preliminary Results*).

[7] *See* Memorandum, ''Carbon and Alloy Steel Wire Rod from the Republic of Korea—Extension of Deadline for Preliminary Results,'' dated March 11, 2021; *see also* Memorandum, ''Carbon and Alloy Steel Wire Rod from the Republic of Korea—Extension of Deadline for the Preliminary Results,'' dated June 17, 2021.

[8] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Carbon and Alloy Steel Wire Rod from the Republic of Korea; 2017–2019,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[9] *Id.*

[10] *See* 19 CFR 351.212(b).

[11] *See* section 751(a)(2)(C) of the Act.

[12] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for POSCO will be equal to POSCO's weighted-average dumping margin established in the final results of this review, except if the rate is less than 0.50 percent, and therefore *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated companies not participating in this review, the cash deposit will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the underlying investigation, but the producer is, then the cash deposit rate will be the rate established for the completed segment for the most recent POR for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 41.10 percent, the all-others rate established in the underlying investigation.[13] These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in connection with these preliminary results to interested parties within five days after the date of publication of this notice in accordance with 19 CFR 351.224(b).

Interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[14] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the time limit for filing case briefs.[15] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[16] Executive summaries should be limited to five pages total, including footnotes. Case and rebuttal briefs should be filed using ACCESS and must be served on interested parties.[17] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[18]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed request for a hearing must be received successfully in its entirety by ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.[19] Hearing requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[20]

Final Results of Review

Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the publication of these preliminary results in the **Federal Register** pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1), unless otherwise extended.[21]

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: July 29, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Comparisons to Normal Value
V. Date of Sale
VI. Constructed Export Price
VII. Normal Value
VIII. Currency Conversion
IX. Recommendation

[FR Doc. 2021–16622 Filed 8–3–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–834]

Certain Carbon and Alloy Steel Cut-To-Length Plate From Italy: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020

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

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that the producers/exporters subject to this administrative review made sales of subject merchandise at less than normal value (NV) during the period of review (POR) May 1, 2019, through April 30, 2020. Additionally, Commerce preliminarily determines that a company for which we initiated a review had no shipments during the POR. Interested parties are invited to comment on these preliminary results.

DATES: Applicable August 4, 2021.

FOR FURTHER INFORMATION CONTACT: Alice Maldonado or David Crespo, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4682 or (202) 482–3693, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 10, 2020, based on timely requests for review in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the antidumping duty order on certain carbon and alloy steel cut-to-length

[13] *See Order,* 81 FR at 23419.

[14] *See* 19 CFR 351.309(c)(1)(ii); *see also* 19 CFR 351.303 (for general filing requirements).

[15] *See* 19 CFR 351.309(d)(1).

[16] *See* 19 CFR 351.309(c)(2) and (d)(2).

[17] *See* 19 CFR 351.303.

[18] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[19] *See* 19 CFR 351.310(c); *see also* 19 CFR 351.303(b)(1).

[20] *See* 19 CFR 351.310(c).

[21] *See* section 751(a)(3)(A) of the Act.

plate (CTL plate) from Italy.[1] This review covers ten producers and/or exporters of the subject merchandise. Commerce selected two companies, NLMK Verona SpA (NVR) and Officine Tecnosider s.r.l. (OTS), for individual examination. The producers and/or exporters not selected for individual examination are listed in the ''Preliminary Results of the Review'' section of this notice.

On July 21, 2020, Commerce tolled preliminary and final results deadlines in administrative reviews by 60 days, thereby extending the deadline for these results until April 1, 2021.[2] On March 10, 2021, Commerce extended the preliminary results of this review by 120 days, until July 30, 2021.[3] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4]

Scope of the Order

The products covered by the order are certain carbon and alloy steel hot-rolled or forged flat plate products not in coils, whether or not painted, varnished, or coated with plastics or other non-metallic substances from Italy. Products subject to the order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7225.40.1110, 7225.40.1180, 7225.40.3005, 7225.40.3050, 7226.20.0000, and 7226.91.5000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive.[5]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) and (2) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price are calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://enforcement.trade.gov/frn/.* A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice.

Preliminary Determination of No Shipments

One company under review, Lyman Steel Company (Lyman), filed a statement reporting that it made no shipments of subject merchandise to the United States during the POR.[6] We were able to confirm Lyman's claim with U.S. Customs and Border Protection (CBP).[7] Consequently, we preliminarily determine that Lyman had no shipments during the POR. Consistent with our practice, we find that it is not appropriate to preliminarily rescind the review with respect to this company, and we will instead complete the review for this company and issue appropriate instructions to CBP based on the final results of this review.[8]

Preliminary Results of the Review

We preliminarily determine that the following weighted-average dumping margins exist for the respondents for the period May 1, 2019, through April 30, 2020:

Exporters/producers	Weighted-average dumping margin (percent)
NLMK Verona SpA	1.21
Officine Tecnosider s.r.l	1.37
Arvedi Tubi Acciaio	1.31
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Rate for Non-Examined Companies

The Act and Commerce's regulations do not address the establishment of a weighted-average dumping margin to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a less-than-fair-value investigation, for guidance when calculating the

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 41540 (July 10, 2020).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[3] *See* Memorandum, ''Carbon and Alloy Steel Cut-to-Length Plate from Italy: Extension of Deadline for Preliminary Results of 2019–2020 Antidumping Duty Administrative Review,'' dated March 10, 2021.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2019–2020 Administrative Review of the Antidumping Duty Order on Certain Carbon and Alloy Steel Cut-To-Length Plate from Italy,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] For a full description of the scope of the order, *see* Preliminary Decision Memorandum.

[6] *See* Lyman's Letter ''Certain Carbon and Alloy Steel Cut-to-Length Plate from Italy; Lyman Steel Company's Certification of No Sales, Shipments, or Entries,'' dated August 7, 2020.

[7] *See* Memorandum, ''Certain Carbon and Alloy Steel Cut-to-Length Plate from Italy (A–475–834),'' dated August 20, 2020.

[8] *See, e.g., Certain Frozen Warmwater Shrimp from Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013,* 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review;* 2012–2013, 79 FR 51306 (August 28, 2014).

weighted-average dumping margin for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding rates that are zero, *de minimis* (*i.e.,* less than 0.5 percent), or determined entirely on the basis of facts available.

Consistent with section 735(c)(5)(A) of the Act, we determined the weighted-average dumping margin for each of the non-selected companies by using the weighted-average dumping margins calculated for NVR and OTS in this administrative review.

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in connection with these preliminary results to interested parties within five days after the date of publication of this notice.[9] Interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[10] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the time limit for filing case briefs.[11] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[12] Case and rebuttal briefs should be filed using ACCESS.[13]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically via ACCESS within 30 days after the date of publication of this notice.[14] Hearing requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[15] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information.[16]

Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless otherwise extended.[17]

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries.[18]

Pursuant to 19 CFR 351.212(b)(1), where the respondent reported the entered value of their U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported. Where the respondent did not report entered value or reported amounts based on estimated sales data, we calculated the entered value in order to calculate the assessment rate. Where either the respondent's weighted-average dumping margin is zero or *de minimis,* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For the companies that were not selected for individual review, we will assign an assessment rate based on the average of the cash deposit rates calculated for NVR and OTS, excluding any rates that are zero, *de minimis,* or determined entirely based on adverse facts available. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

Commerce's ''automatic assessment'' will apply to entries of subject merchandise during the POR produced by companies included in the final results of this review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[19]

Further, if we continue to find, in the final results, that Lyman had no shipments of subject merchandise during the POR, we will instruct CBP to liquidate any suspended entries that entered under their AD case number (*i.e.,* at that exporter's rate) or at the all-others rate, if there is no rate for the intermediate company(ies) involved in the transaction.

Consistent with its recent notice,[20] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the exporters listed above will be equal to the weighted-average dumping margin established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for companies not participating in this review, the cash deposit rate will continue to be the company-specific cash deposit rate published for the most recently completed segment; (3) if the exporter is not a firm covered in this review or the original less-than-fair-

[9] *See* 19 CFR 351.224(b).

[10] *See* 19 CFR 351.309(c).

[11] Commerce is exercising its discretion, under 19 CFR 351.309(d)(1), to alter the time limit for filing of rebuttal briefs.

[12] *See* 19 CFR 351.309(c)(2) and (d)(2).

[13] *See* 19 CFR 351.303.

[14] *See* 19 CFR 351.310(c).

[15] *See* 19 CFR 351.310(d).

[16] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[17] *See* Section 751(a)(3)(A) of the Act.

[18] *See* 19 CFR 351.212(b).

[19] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[20] *See Notice of Discontinuation of Policy to Issue Liquidation Instructions After 15 Days in Applicable Antidumping and Countervailing Duty Administrative Proceedings,* 86 FR 3995 (January 15, 2021).

value (LTFV) investigation, but the producer is, then the cash deposit rate will be the cash deposit rate established for the most recently completed segment for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 6.08 percent, the all-others rate established in the LTFV investigation.[21] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 29, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Preliminary Determination of No Shipments
V. Companies Not Selected for Individual Examination
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Recommendation

[FR Doc. 2021–16624 Filed 8–3–21; 8:45 am]

BILLING CODE 3510–DS–P

[21] *See Certain Carbon and Alloy Steel Cut-To-Length Plate from Austria, Belgium, France, the Federal Republic of Germany, Italy, Japan, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Determinations for France, the Federal Republic of Germany, the Republic of Korea, and Taiwan, and Antidumping Duty Orders,* 82 FR 24096, 24098 (May 25, 2017).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–863]

Large Diameter Welded Pipe From Canada: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2018–2020

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

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on large diameter welded pipe (welded pipe) from Canada. The period of review (POR) is August 27, 2018, through April 30, 2020. The review covers forty-one producers or exporters of the subject merchandise. We preliminarily determine that sales of subject merchandise were made at prices below normal value (NV) during the POR. Interested parties are invited to comment on these preliminary results.

DATES: Applicable August 4, 2021.

FOR FURTHER INFORMATION CONTACT: Joseph Dowling, 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) 482–1646.

SUPPLEMENTARY INFORMATION:

Background

On May 2, 2019, Commerce published the antidumping duty order on welded pipe from Canada.[1] On July 10, 2020, in accordance with 19 CFR 351.221(c)(i), Commerce initiated an administrative review of the *Order,* covering 41 producers or exporters of the subject merchandise.[2] On August 5, 2020, we selected Evraz Inc. NA [3] as the sole mandatory respondent for this administrative review.[4] On July 22, 2020, Commerce tolled all deadlines in administrative reviews by 60 days.[5] Pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), Commerce determined that it was not practicable to complete the preliminary results of this review within 245 days and extended the deadline for the preliminary results of this review by 120 days, until July 30, 2021.[6]

For a detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[7] The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/.*

Scope of the Order

The product covered by this *Order* is welded pipe from Canada. For a full description of the scope, *see* the Preliminary Decision Memorandum.

Preliminary Determination of No Shipments

One producer and/or exporter under review, Canam (St Gedeon) (Canam), properly filed a certification reporting that it made no shipments of subject merchandise during the POR.[8] We received no information from CBP that contradicted Canam's no-shipment

[1] *See Large Diameter Welded Pipe from Canada: Antidumping Duty Order,* 84 FR 18775 (May 2, 2019) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 41540 (July 10, 2020) (*Initiation Notice*).

[3] In the underlying less-than-fair-value (LTFV) investigation, Commerce determined that Evraz Inc. NA, Evraz Inc. NA Canada, and the Canadian National Steel Corporation (collectively, Evraz) comprise a single entity. *See Large Diameter Welded Pipe from Canada: Antidumping Duty Order,* 84 FR 18775 (May 2, 2019) (*Order*). There is no information on this record of this review that requires reconsideration of this single entity determination.

[4] *See* Memorandum, ''Antidumping Duty Administrative Review of Large Diameter Welded Pipe from Canada, 2018–2020—Respondent Selection,'' dated August 5, 2020.

[5] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 22, 2020.

[6] *See* Memorandum, ''Large Diameter Welded Pipe from Canada: Extension of Deadline for Preliminary Results of 1st Antidumping Duty Administrative Review,'' dated March 10, 2021; *see also* Memorandum, ''Large Diameter Welded Pipe from Canada: Extension of Deadline for Preliminary Results of 1st Antidumping Duty Administrative Review,'' dated June 28, 2021.

[7] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Large Diameter Welded Pipe from Canada; 2018–2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[8] In the *Initiation Notice,* this company was listed as Canam (St Gedeon). However, in its certification of no shipments, it noted that Canam (St Gedeon) is a plant location and not its legal name. It also noted that it had recently undergone a corporate restructuring and is now named Canam Group Inc., which is the successor entity to Canam Group Inc. f/k/a Canam Buildings and Structures Inc. *See* Canam's Letter, ''No Shipments Letter for Canam Group Inc. f/k/a Canam Buildings and Structures Inc.,'' dated August 7, 2020.

claim.[9] Therefore, we preliminarily determine that this company did not have shipments of subject merchandise during the POR. Consistent with Commerce's practice,[10] Commerce finds that it is not appropriate to rescind the review with respect to this company, but rather, to complete the review and issue appropriate instructions to CBP based on the final results of this review.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. Export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. A list of topics included in the Preliminary Decision Memorandum is included as an appendix to this notice.

Preliminary Results of the Review

We preliminarily determine that the following weighted-average dumping margins exist for the period of August 27, 2018, through April 30, 2020:

Exporter or producer	Weighted-average dumping margin (percent)
Evraz Inc. NA	14.33
Non-Selected Companies Under Review [11]	14.33

Rate for Non-Selected Companies

For the weighted-average dumping margin for non-selected respondents in an administrative review, generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation. Under section 735(c)(5)(A) of the Act, the all-others rate is normally an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely on facts available. We preliminarily calculated a weighted-average dumping margin for Evraz that was not zero, *de minimis,* or based on facts available. Accordingly, we have preliminarily applied the weighted-average dumping margin calculated for Evraz as the weighted-average dumping margin for the non-individually examined companies.

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to parties within five days after public announcement of the preliminary results.[12]

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[13] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.[14] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[15] Executive summaries should be limited to five pages total, including footnotes. Case and rebuttal briefs should be filed using ACCESS [16] and must be served on interested parties.[17] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[18]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed document must be received successfully in its entirety by ACCESS by 5 p.m. Eastern Standard Time within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Commerce intends to issue assessment instructions to CBP 35 days after the date of publication of the final results of this administrative review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

If Evraz's weighted-average dumping margin is above *de minimis* (*i.e.,* 0.50 percent), upon completion of the final results, Commerce will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of sales. Where we do not have entered values for all U.S. sales to a particular importer, we will calculate a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to that importer and dividing this amount by the total quantity sold to that importer.[19] To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculate importer-specific *ad valorem* ratios based on the estimated entered value. Where Evraz's weighted-average dumping margin is zero or *de minimis,* or an importer-specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[20] For the companies which were not selected for individual examination, we intend to direct CBP to assess antidumping duties at a rate equal to the weighted-average dumping margin determined for Evraz in the final results.

For entries of subject merchandise during the POR produced by Evraz for

[9] *See* Memorandum, ''No Shipment Inquiry with Respect to the Company below during the Period 08/27/2018 through 04/30/2020,'' dated August 20, 2020.

[10] *See, e.g., Certain Frozen Warmwater Shrimp from Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments;* 2012–2013, 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012–2013,* 79 FR 51306 (August 28, 2014).

[11] *See* Appendix II.

[12] *See* 19 CFR 351.224(b).

[13] *See* 19 CFR 351.309(c)(1)(ii).

[14] *See* 19 CFR 351.309(d)(1) and (2); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[15] *See* 19 CFR 351.309(c)(2) and (d)(2).

[16] *See* 19 CFR 351.303.

[17] *See* 19 CFR 351.303(f).

[18] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[19] *See* 19 CFR 351.212(b)(1).

[20] *See* 19 CFR 352.106(c)(2); *see also Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[21]

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future cash deposits of estimated duties, where applicable.[22]

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the companies listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rates will be zero; (2) for previously reviewed or investigated companies not covered in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which the company was reviewed; (3) if the exporter is not a firm covered in this review or in the LTFV investigation, but the manufacturer is, then the cash deposit rate will be the company-specific rate established for the most recently-completed segment of this proceeding for the manufacturer of subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 12.32 percent, the all-others rate established in the LTFV investigation.[23] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised by the parties in the written comments, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

[21] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[22] *See* section 751(a)(2)(C) of the Act.

[23] *See Order.*

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

These preliminary 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)(4).

Dated: July 28, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Preliminary Determination of No Shipments
V. Rate for Non-Examined Companies
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Recommendation

Appendix II

Review-Specific Rate Applicable to Companies Not Selected for Individual Review

1. Acier Profile SBB Inc
2. Aciers Lague Steels Inc
3. Amdor Inc
4. BPC Services Group
5. Bri-Steel Manufacturing
6. Canada Culvert
7. Canadian National Steel Corp
8. Cappco Tubular Products Canada Inc
9. CFI Metal Inc
10. Dominion Pipe & Piling
11. Enduro Canada Pipeline Services
12. Fi Oilfield Services Canada
13. Forterra
14. Gchem Ltd
15. Graham Construction
16. Groupe Fordia Inc
17. Grupo Fordia Inc
18. Hodgson Custom Rolling
19. Hyprescon Inc
20. Interpipe Inc
21. K K Recycling Services
22. Kobelt Manufacturing Co
23. Labrie Environment
24. Les Aciers Sofatec
25. Lorenz Conveying P
26. Lorenz Conveying Products
27. Matrix Manufacturing
28. MBI Produits De Forge
29. Nor Arc
30. Peak Drilling Ltd
31. Pipe & Piling Sply Ltd
32. Pipe & Piling Supplies
33. Prudental
34. Prudential
35. Shaw Pipe Protecction
36. Shaw Pipe Protection
37. Tenaris Algoma Tubes Facility
38. Tenaris Prudential
39. Welded Tube of Can Ltd

[FR Doc. 2021–16625 Filed 8–3–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB265]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Whiting Joint Committee and Advisory Panel via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Thursday, August 19, 2021 at 9.30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/4426583000054968 44.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Whiting Committee and Advisory Panel will receive Fishing Year 2020 Annual Monitoring Report from the Whiting Plan Development Team. They will identify and discuss management priority recommendations to be considered at the September 2021 Council meeting. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues

specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: July 30, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–16652 Filed 8–3–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB294]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Spiny Dogfish Advisory Panel will hold a public meeting.

DATES: The meeting will be held on Thursday, August 19, 2021, from 10 a.m. to 1 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meeting will be held via webinar. Webinar connection information will be available at: *https://www.mafmc.org/council-events.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their website at *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is for the Advisory Panel to create a Fishery Performance Report including advisor input on related specifications and management measures.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shelley Kimbel-Spedden at the Council Office, (302) 526–5251, at least 5 days prior to the meeting date.

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

Dated: July 30, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–16648 Filed 8–3–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Availability of a Draft Environmental Impact Statement for the Proposed Lake Ontario National Marine Sanctuary; Announcement of Public Meetings

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of virtual public meetings; correction.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) has prepared a draft environmental impact statement (DEIS) for the proposed designation of a national marine sanctuary to manage a nationally significant collection of shipwrecks and other underwater cultural resources in New York's eastern Lake Ontario and the Thousand Islands region of the St. Lawrence River. NOAA previously announced public meetings during the comment period, and is replacing the two in-person meetings with additional virtual meetings and providing registration links for the previously announced virtual meetings.

DATES: NOAA will continue to accept comments received by September 10, 2021. NOAA will conduct a total of four virtual public meetings on the following dates:

(1) Date: Wednesday, August 18, 2021

Location and time: Virtual Meeting, 6:30–8:30 p.m. EDT
Registration via this link: https://attendee.gotowebinar.com/register/8226916950939600400
By phone: (415) 655–0060
Access Code: 439–509–724. *Audio PIN:* Shown after joining the webinar

(2) Date: Thursday, August 19, 2021

Location and time: Virtual Meeting, 6:30–8:30 p.m. EDT
Registration via this link: https://attendee.gotowebinar.com/register/8864690869654406928
By phone: (914) 614–3221
Access Code: 237–285–132. *Audio PIN:* Shown after joining the webinar

(3) Date: Tuesday, August 24, 2021

Location and time: Virtual Meeting, 2:30 to 4 p.m. EDT
Registration via this link: https://register.gotowebinar.com/register/5067664901003984652
Access code: 346–751–009. *Audio PIN:* Shown after joining the webinar
By phone: (562) 247–8422, *PIN:* 346–751–009

(4) Date: Thursday, August 26, 2021

Location and time: Virtual Meeting, 6:30 p.m. to 8 p.m. EDT
Registration via this link: https://register.gotowebinar.com/register/2978792919345892364
By phone: (415) 655–0052, *PIN:* 819–641–913

ADDRESSES: Copies of the DEIS can be downloaded or viewed on the internet at *www.regulations.gov* (search for docket NOAA–NOS–2021–0050) or at *http://sanctuaries.noaa.gov/lake-ontario/.* Copies can also be obtained by contacting Ellen Brody (in the **FOR FURTHER INFORMATION CONTACT** section of this notice).

FOR FURTHER INFORMATION CONTACT: Ellen Brody, Great Lakes Regional Coordinator, address: 4840 South State Road, Ann Arbor, MI 48108–9719; phone: 734–276–6387; email: *ellen.brody@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

In accordance with the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) and the NMSA (16 U.S.C. 1434), NOAA prepared a DEIS for a proposed national marine sanctuary in New York's eastern Lake Ontario and the Thousand Islands region of the St. Lawrence River. NOAA announced the availability of the DEIS in a notice issued on July 7, 2021 (86 FR 35757). In that notice, NOAA announced there would be four public meetings, two of which were planned to be virtual meetings, and two of which NOAA

planned to hold in person. When the notice was issued, NOAA included a caveat to the in-person meetings stating ''A virtual meeting platform may substitute if public safety concerns remain to prevent the spread of COVID–19.''

NOAA has determined that the two meetings previously scheduled for August 18, 2021 and August 19, 2021 will now be conducted virtually. Interested parties should register to attend a virtual meeting via the information provided in the **DATES** section of this notice or at *https://sanctuaries.noaa.gov/lake-ontario/.*

(Authority: 16 U.S.C. 1431 *et seq.*)

Rebecca R. Holyoke,

Acting Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2021–16639 Filed 8–3–21; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Technical Information Service

[Docket No.: 191122–0088]

Opportunity To Enter Into a Joint Venture Partnership With the National Technical Information Service for Data Innovation Support

AGENCY: National Technical Information Service, Department of Commerce.

ACTION: Notice.

SUMMARY: The National Technical Information Service (NTIS) requests proposals from interested private-sector organizations to assist Federal agencies in the development and implementation of innovative ways to collect, connect, access, secure, analyze, disseminate and enable effective and efficient use of data to address unique and complex national data priorities. Specifically, NTIS is interested in partnering with organizations that have specialized skills and capabilities in applied data science areas, such as artificial intelligence, machine learning, robotics, and cybersecurity, to assist the Federal government in leveraging data as a strategic asset to achieve Federal agency mission outcomes. Organizations that are selected in accordance with the evaluation criteria and selection process set forth in this notice will be invited to enter into a joint venture partnership agreement with NTIS to be eligible to compete for Federal data service opportunities identified by NTIS in cooperation with other Federal agencies. In accordance with the President's Executive Order on *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,* E.O. 13985 of Jan 20, 2021, NTIS encourages all individuals and organizations to apply who meet the listed qualifications and requirements in this notice, including those who come from underserved communities, such as Black, Latino, Indigenous and Native American, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality and the organizations that support these individuals and groups.

DATES: Proposals will be received and evaluated on an ongoing basis. Proposals will not be accepted after August 24, 2024. This Notice replaces the notice published on December 13, 2019, 84 FR 68147. Applicants that have already submitted proposals under the 2019 notice do not need to resubmit under this notice.

ADDRESSES: Submit proposals electronically, with the subject line ''Opportunity to Enter into a Joint Venture Partnership with the National Technical Information Service for Data Innovation Support'', by emailing both *OpportunityAnnouncement@ntis.gov* and Randy Caldwell at *rcaldwell@ntis.gov.*

FOR FURTHER INFORMATION CONTACT: Randy Caldwell at (703) 605–6321, or by email at *rcaldwell@ntis.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction/Background for Potential Joint Venture Partners (JVPs)

NTIS, an agency of the U.S. Department of Commerce, is seeking proposals from potential JVPs that can work with NTIS to assist Federal agencies to leverage innovative ways to collect, connect, access, secure, analyze, disseminate and enable effective and efficient use of data to address unique and complex national data priorities.

Federal agencies are currently addressing national issues in such areas as fraud detection, improper payments, public services, health and safety, cybersecurity, technology transfer, supply chain optimization, and internal requirements to operate more effectively and efficiently. Addressing these mission-critical data issues requires new capabilities in machine learning, artificial intelligence, predictive analytics and other advanced data science expertise. *See* OMB M–19–18 [1] and Executive Order 13859.[2] Federal agencies that need the data services of NTIS and its JVPs require holistic solutions that may require the application of multiple data and technological capabilities in new and innovative ways in order to support the agencies' strategic plans and mission-critical priorities. Many of the challenges facing Federal agencies are at the intersection of data science and information technology (IT) modernization. Solutions often require related capabilities in emerging technologies, innovation, change management, and agile delivery methods. Mission areas that NTIS supports include, but are not limited to, fraud detection, public services, health and safety, technology transfer, and national security.

Activities conducted by NTIS and its JVPs in support of other Federal agencies may include: (1) Designing, testing, analyzing, or demonstrating the application of Federal data and data services, either alone or in combination with non-Federal data; (2) based on Federal data or the use of Federal data in some combination with open Federal data and non-Federal data, facilitating the creation of suites of products, platforms, and services that assist Federal agencies in meeting the needs of businesses, innovators, government agencies, and others; and (3) otherwise enhancing data discovery and usability, data interoperability and standards, data analytics and forecasting, or data infrastructure and security. Projects that can be accomplished by a Federal agency via a commercial-off-the-shelf (COTS) procurement or acquisition action will not be conducted by NTIS with its JVPs.

Organizations that enter into joint venture partnership agreements with NTIS, pursuant to this notice, will have opportunities to engage in early discussions about projects with NTIS and the sponsoring Federal agencies and may subsequently compete for the opportunity to work with NTIS to provide data services on specific projects under a merit-based selection process established by NTIS.

Under a separate notice that will be published in the **Federal Register** (''assistive technologies JVPs notice''), NTIS will accept proposals from interested private-sector organizations to become a JVP eligible to work with

[1] *https://www.whitehouse.gov/wp-content/uploads/2019/06/M-19-18.pdf.*

[2] *https://www.federalregister.gov/documents/2019/02/14/2019-02544/maintaining-american-leadership-in-artificial-intelligence.*

NTIS on projects involving assistive technologies. JVPs selected under the instant notice will not be eligible to compete for assistive technology project opportunities with NTIS unless they also apply and are selected under the assistive technologies JVPs notice. Organizations that enter into JVP agreements with NTIS pursuant to the assistive technologies notice will not be eligible to compete for data innovation opportunities with NTIS unless they also apply and are selected under the instant notice. Organizations selected under the instant notice will be eligible to work with NTIS on projects involving the types of data innovation described in this notice.

The Secretary of Commerce (Secretary) has delegated to NTIS authority to operate as a permanent clearinghouse of scientific, technical, and engineering information and to collect and disseminate such information. 15 U.S.C. 1152. The National Technical Information Act of 1988, codified at 15 U.S.C. 3704b, additionally accorded the Secretary, acting through NTIS, the authority to enter into joint ventures, and declared the clearinghouse to be a permanent Federal function that could not be privatized without Congressional approval. The National Technical Information Act of 1988 was amended by section 506(c) of the American Technology Preeminence Act of 1991 (Pub. L. 102–245), which directed NTIS to focus on developing new electronic methods and media for information dissemination.

As the nature and scope of information and data dissemination have changed, NTIS has continued to focus on innovations to address these changes. New capabilities are available in application program interfaces (APIs) as conduits for data dissemination that have significantly improved data use, interoperability, and accessibility. Artificial intelligence, machine learning, and predictive analytics are transforming how data are analyzed and managed to support national priorities in fraud detection, emergency preparedness, cybersecurity, citizen services, and in promoting health and public safety.

Using its joint venture authority, NTIS has established a unique joint venture partnership program that has resulted in a number of innovative data service projects across the Federal government that allow other Federal agencies to address national priorities more efficiently and effectively.

Specifically, through NTIS' joint venture partnership program, NTIS will (1) accelerate private-sector use of Federal government data, either alone or in combination with non-Federal data, for the development and use of new and improved data products and services, and (2) accelerate the Federal government's use of data to improve the effectiveness and efficiency of Federal programs and thus improve mission outcomes.

The NTIS joint venture partnership program enables NTIS to structure joint venture partnership agreements with the private sector and interagency agreements with Federal agencies that offer the best combination of speed, agile applications development, and performance for delivering integrated innovative data services and solutions. NTIS manages joint venture projects in a highly flexible, interactive, and collaborative manner with its customer Federal agencies and JVPs throughout the project lifecycle.

Joint ventures are not procurements or acquisitions and do not result in contracts under the Federal Acquisition Regulation (FAR). Joint ventures involve the investment of resources by NTIS and its JVPs, with a formal agreement for the sharing of revenues associated with the venture. The joint venture partnerships provide data services that allow customer Federal agencies to accelerate the time it takes to achieve mission outcomes. The joint venture partnerships accomplish this by using innovative and creative methods of collecting, connecting, accessing, securing, analyzing, disseminating and enabling effective and efficient use of Federal data and non-Federal data.

II. General Scope

Technical Requirements

Proposals must address at least one of the following two technical requirements by demonstrating the proposer's capabilities to deliver data-driven innovations. The proposer must explicitly state in the proposal which area(s) are addressed.

1. *Innovations in the use of data and data services to leverage data as a strategic asset to improve business processes and mission outcome.* The proposal must include a description of how the proposer would contribute innovations in the use of data and data services. The scope of this area includes data science and engineering innovations and the ability to integrate and deliver complete data-driven solutions associated with (a) making it easier to use data through data cleansing and improved interoperability; (b) searching, discovering, combining, analyzing, disseminating, and using Federal government data, either alone or in combination with non-Federal data, in new ways; and (c) implementing innovative and secure data infrastructures to advance artificial intelligence (AI) and machine learning for enabling cybersecurity, and creating cloud based analytic data platforms that deliver capabilities for data analytics through highly scalable infrastructure.

2. *Analysis, interpretation, and understanding of data, as well as meaningful application of the analysis and interpretation, to automate business processes, predict future events and prescribe potential solutions.* The proposal must describe how the proposer would use AI, machine learning, and robotics to improve the analysis, interpretation, understanding, and application of either static or real time data to achieve innovations in business processes automation, supply chains, and overall mission outcome.

Additional Requirements

NTIS will enter into joint venture partnership agreements in accordance with all relevant provisions of applicable Federal law. Any proposal that has the appearance of circumventing the FAR or other agency acquisition requirements will be determined to be non-responsive to this notice during the initial phase of the selection process and will not be considered further. Proposers must acknowledge and address the following terms in their proposals:

- Data received from a Federal agency and from non-Federal organizations as part of a project performed by NTIS with a JVP may only be accessed and utilized for project purposes consistent with all applicable statutory and regulatory provisions and all relevant agreements.
- Federal agencies and private-sector organizations that provide data as part of a project performed by NTIS with a JVP will retain ownership of the data rights. Federal agencies and private-sector organizations may be requested to provide licenses to use the data for the purposes of a project.
- At a minimum, systems, programs, and applications included in the proposal must comply with the documented security assessment and authorization (A&A) policies issued by the Office of Management and Budget (OMB), standards and guidance issued by the National Institute of Standards and Technology (NIST), and the Federal Information Security Modernization Act of 2014 (FISMA) (44 U.S.C. 3551 *et seq.*), before the systems, programs, and applications are offered to Federal agencies under a joint venture partnership.

• JVPs who are selected and enter into joint venture partnership agreements pursuant to this notice will be eligible to submit proposals for specific project opportunities. Eligible JVPs interested in such opportunities will be required to submit a proposal in response to an opportunity announcement for specific projects within a short time period, typically two to three weeks.

• Proposers must have the ability to accept electronic fund transfers.

• NTIS will not guarantee that any revenue will be generated for the JVP merely by entering into a joint venture partnership agreement with NTIS.

• Proposers must have the ability to fund their portion of any projects commenced pursuant to a joint venture partnership agreement for a period of time, which may differ for individual projects, due to Federal accrual accounting practices. NTIS does not allow (and has never offered) financial incentives for entering into joint venture partnership agreements. NTIS will not provide advance payments to JVPs.

III. Requested Response

NTIS seeks to enter into joint venture partnership(s) with one or more partners to assist Federal agencies in furthering their missions in innovative and creative ways by enabling government agencies and the public with improved access to, or analysis, collection, or use of Federal data and data services, either alone or in combination with non-Federal data. NTIS and its JVPs provide data services for speedy execution of innovative projects, typically involving one or more of the following attributes: (a) First or early use of emerging technology; (b) complexity of solution architecture, interoperability, and/or security; (c) agile applications development and systems operations, which require adaptive scoping; or (d) custom solutions to meet unique requirements without COTS solutions.

Proposers are encouraged to include proposed teams of private-sector organizations, which may include small and medium-size enterprises and start-ups that bring unique and innovative capabilities for delivering data science capabilities. Proposals should describe any proposed teaming arrangements and solution integration capabilities, including the relationships among the parties, how the team would function, and how the team may be augmented to fill missing capabilities. Although teaming arrangements are encouraged, the JVP itself will be expected to provide at least 50 percent of the labor on each project for which it is selected. NTIS will evaluate each proposal and may solicit oral presentations from some or all proposers. Where appropriate, NTIS, in its discretion, may reach out to selected JVPs for teaming arrangements on future projects that involve emerging and/or cutting-edge capabilities that fall within NTIS' mission.

Proposal Submission Information

The proposal is a word-processed document of no more than fifteen (15) single-spaced pages responsive to the evaluation criteria set forth below. Any pages submitted beyond the 15-page limit will not be considered. Each proposal page layout should be 8.5 inches by 11 inches with 1-inch margins. The font for the proposal should be Times New Roman 12 point or similar font in readable size (no less than 10 point). All submissions must be made in electronic format and submitted in accordance with the **ADDRESSES** section above. All proposals are subject to the False Claims Amendments Act of 1986, 31 U.S.C. 3729 and 18 U.S.C. 287, as well as the False Statements Accountability Act of 1996, 18 U.S.C 1001. In accordance with Federal appropriations law, an authorized representative of the selected proposer(s) may be required to provide certain certifications regarding Federal felony and Federal criminal tax convictions, unpaid Federal tax assessments, and delinquent Federal tax returns.

Proposal Technical, Administrative and Business Information

The proposal must address each of the evaluation criteria set forth in the following section and should include all of the information set forth in this section in a manner sufficient to allow each section to be reviewed against the evaluation criteria set forth below. Each section of the proposal should include a brief title or description of its content.

(1) The proposal to become a JVP must include a capability statement that describes the nature and scope of the organization's expertise to perform data services to address mission-critical Federal data requirements. The proposal must include: (a) A description of technical capabilities in each area of data innovation that the proposer and, where applicable, its team, will address; (b) examples of up to three major projects where the proposer and, where applicable, its team, have demonstrated data innovations using the technical capabilities; if the proposer and, where applicable, its team, have not conducted projects in which they have demonstrated data innovations using the technical capabilities, the proposer should include instead a description of how it would go about doing so; (c) a description of the professional accomplishments, skills, certifications, and training of the personnel proposed to provide the technical capabilities and perform the work proposed in the proposal, including each individual whose innovative technical capabilities are critical to the development or execution of joint venture projects in a substantive and measurable way; and (d) a description of the resources, such as staff, partnerships, integration and project management capabilities, contracts, or technologies, that the proposer would use to achieve these innovations. This information will be considered against evaluation criteria 1 through 3 below.

(2) The proposal may include any other information that the proposer thinks will assist reviewers in their evaluation of the proposal against the evaluation criteria described below.

To the extent permitted by law, including the Freedom of Information Act (FOIA), 5 U.S.C. 552, NTIS will not disclose confidential or proprietary information provided and clearly marked in any proposal submitted in response to this notice without providing the organization that submitted such information the opportunity to object to the potential release of the information. If NTIS receives a request for disclosure of confidential or proprietary information, it will promptly notify the submitting organization in writing and give it an opportunity to demonstrate that NTIS should withhold the information in accordance with Department of Commerce FOIA regulations (15 CFR part 4).

Evaluation Criteria

The evaluation criteria for the proposals are as follows:

(1) Rationality (0–35 points).

The extent to which the logic and soundness of the proposer's approach to enable data innovations that will address Federal data priorities by (a) advancing the use of data as a strategic asset to achieve mission outcome and support evidence-based policies; (b) transforming and optimizing supply chains through the use of data science capabilities; (c) promoting data governance and standardization; and (d) creating new capabilities for data discovery, data set search, and interoperability to connect and derive new insights for predictive analytics and prescriptive actions.

(2) Technical Merit of Contribution (0–30 points).

The technical effectiveness and innovation of the proposed capabilities

and past work or plans for providing such capabilities described in the proposal and the extent to which they would contribute to the fields of data science, AI, engineering, or best practices relevant to the services to be provided by NTIS and its JVPs as described in the General Scope section of this announcement.

(3) Organizational Qualifications and Resource Availability (0–35 points).

The likelihood that the professional accomplishments, data services and solution integration delivery experience, skills, certifications, and training of the personnel proposed to provide the technical capabilities and perform the work proposed in the proposal, including all individuals whose innovative technical capabilities are critical to the development or execution of joint venture projects in a substantive and measurable way as identified in the proposal, will contribute to the successful execution of projects; and the extent to which the proposer has access to the necessary equipment, tools, facilities, technologies, and overall support and resources to accomplish proposed objectives and work jointly with NTIS to accomplish project goals.

Evaluation and Selection Process

All proposals received before the end date set forth in the **DATES** section of this notice will be reviewed to determine whether they are submitted by a private-sector organization (eligible), contain all required technical, business and administrative information (complete), and are responsive to this notice. Proposals determined to be ineligible, incomplete, and/or non-responsive based on the initial screening will be eliminated from further review. However, NTIS, in its sole discretion, may continue the review process for a proposal that is missing non-substantive information that can easily be rectified or cured.

All proposals that are determined to be eligible, complete, and responsive will proceed for full reviews in accordance with the review and selection process set forth below.

At least three (3) objective individuals, knowledgeable about the particular technical areas described in the proposal, will review the merits of each proposal based on the evaluation criteria. The reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus. NTIS may solicit oral presentations from some or all proposers.

The Selecting Official, who is the NTIS Deputy Director or designee, will make final proposal selections, taking into consideration the results of the reviewers' evaluations, relevance to the scope and objectives described in this notice, the distribution of proposals across technical areas, and the distribution of proposers among a diverse set of qualified organizations. A diverse set of qualified organizations would include large, medium, and small organizations that may be for-profit or non-profit and that have both unique and discrete data science capabilities and specialized expertise and experience in integrating such capabilities for holistic, complete solutions.

Notification of Results

Unsuccessful proposers will be notified in writing. Proposers whose proposals are selected will be notified and will be provided with a standard NTIS joint venture partnership agreement for execution. Each joint venture partnership agreement entered into between a selected proposer and NTIS will incorporate the selected proposer's proposal by reference. NTIS will not be responsible for any costs incurred by any proposer prior to execution of a joint venture partnership agreement.

Dated: July 30, 2021.

Gregory Capella,

Deputy Director, National Technical Information Service.

[FR Doc. 2021–16581 Filed 8–3–21; 8:45 am]

BILLING CODE 3510–04–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–C–2021–0036]

Performance Review Board (PRB)

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: In conformance with the Civil Service Reform Act of 1978, the United States Patent and Trademark Office announces the appointment of persons to serve as members of its Performance Review Board.

ADDRESSES: Office of Human Resources, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Lari B. Washington—Acting Director, Human Capital Management at (571) 272–5187.

SUPPLEMENTARY INFORMATION: The membership of the United States Patent and Trademark Office Performance Review Board is as follows:

Coke M. Stewart, Chair, Performing the Functions and Duties of the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office

Frederick W. Steckler, Vice Chair, Chief Administrative Officer, United States Patent and Trademark Office

Andrew I. Faile, Acting Commissioner for Patents, United States Patent and Trademark Office

David S. Gooder, Commissioner for Trademarks, United States Patent and Trademark Office

Dennis J. Hoffman, Chief Financial Officer, United States Patent and Trademark Office

Henry J. Holcombe, Chief Information Officer, United States Patent and Trademark Office

David L. Berdan, General Counsel, United States Patent and Trademark Office

Mary Critharis, Chief Policy Officer and Director for International Affairs, United States Patent and Trademark Office

Gerard F. Rogers, Chief Administrative Trademark Judge, United States Patent and Trademark Office

Scott R. Boalick, Chief Administrative Patent Judge, United States Patent and Trademark Office

Bismarck Myrick, Director of the Office of Equal Employment Opportunity and Diversity, United States Patent and Trademark Office

Cara Duckworth, Acting Chief Communications Officer, United States Patent and Trademark Office

Alternates:

Richard Seidel, Deputy Commissioner for Patents, United States Patent and Trademark Office

Greg Dodson, Deputy Commissioner for Trademark Administration, United States Patent and Trademark Office

Andrew Hirshfeld,

Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2021–16586 Filed 8–3–21; 8:45 am]

BILLING CODE 3510–16–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Publication of FY 2018 Service Contract Inventory

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice of public availability of FY 2018 service contract inventory.

SUMMARY: In accordance with section 734 of Division C of the Consolidated Appropriations Act of 2010, the Bureau of Consumer Financial Protection (Bureau) is publishing this notice to advise the public of the availability of the FY 2018 service contract inventory. This inventory provides information on service contract actions over $25,000, which the Bureau funded during FY 2018. The information is organized by function to show how contracted resources were used by the agency to support its mission. The inventory has been developed in accordance with the guidance issued by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). The Bureau has posted its inventory on the Bureau's Open Government homepage at the following link: *http://www.consumerfinance.gov/about-us/doing-business-with-us/past-awards/.*

FOR FURTHER INFORMATION CONTACT: Nikki Burley, Senior Procurement Analyst, Office of Procurement, at 202–435–0329, or *Nikki.Burley@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

Dated: July 30, 2021.

Jocelyn Sutton,

Deputy Chief of Staff, Bureau of Consumer Financial Protection.

[FR Doc. 2021–16634 Filed 8–3–21; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC21–109–000.
Applicants: Inspire Energy Holdings, LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act of Inspire Energy Holdings, LLC.
Filed Date: 7/28/21.
Accession Number: 20210728–5194.
Comments Due: 5 p.m. ET 8/18/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER21–2139–001.
Applicants: Florida Power & Light Company.
Description: Tariff Amendment: Amendment to FPL & Seminole NITSA No. 162 New Delivery Point to be effective 7/1/2021.
Filed Date: 6/16/21.
Accession Number: 20210616–5095.
Comments Due: 5 p.m. ET 7/30/21.

Docket Numbers: ER21–2513–001.
Applicants: Golden Spread Electric Cooperative, Inc.
Description: Compliance filing: Errata to Order No. 676–I Compliance and Waiver to be effective 12/31/9998.
Filed Date: 7/29/21.
Accession Number: 20210729–5087.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2540–000.
Applicants: San Diego Gas & Electric Company.
Description: § 205(d) Rate Filing: Revisions to Appendices VII and IX for Retail Rate Design to be effective 1/1/2022.
Filed Date: 7/29/21.
Accession Number: 20210729–5001.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2541–000.
Applicants: Gulf Power Company.
Description: Request for continued Limited Waiver of Gulf Power Company.
Filed Date: 7/27/21.
Accession Number: 20210727–5176.
Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2542–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3340R1 Otter Tail Power Company NITSA and NOA to be effective 7/1/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5004.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2543–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original WMPA, Service Agreement No. 6129; Queue No. AF1–287 to be effective 6/29/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5008.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2544–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 1266R12 Kansas Municipal Energy Agency NITSA and NOA to be effective 7/1/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5026.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2545–000.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: § 205(d) Rate Filing: Rate Schedule FERC No. 332 between Tri-State and Continental to be effective 7/30/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5037.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2546–000.
Applicants: Rochester Gas and Electric Corporation, New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: Joint 205 EPCA among NYISO, RG&E, NextEra for Empire State Line SA2635, CEII to be effective 7/15/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5052.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2547–000.
Applicants: AEP Texas Inc.
Description: § 205(d) Rate Filing: AEPTX–AP Solar 4 (Charger Solar) 1st A&R Generation Interconnection Agreement to be effective 7/13/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5054.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2548–000.
Applicants: ISO New England Inc., New England Power Company.
Description: § 205(d) Rate Filing: ISO–NE and NEP: First Revised Service Agreement No. LGIA–ISONE/NEP–15–04 to be effective 3/19/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5055.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2549–000.
Applicants: DDP Specialty Electronic Materials US, Inc.
Description: Compliance filing: Rate Schedule No. 1 Market Based Rate Tariff to be effective 1/4/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5064.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2550–000.
Applicants: Specialty Products US, LLC.
Description: Compliance filing: Rate Schedule No. 1 Market Based Rate Tariff to be effective 1/4/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5065.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2551–000.
Applicants: NorthWestern Corporation.
Description: Tariff Cancellation: Cancellation of SA 305 16th Rev—NITSA with Stillwater Mining Company to be effective 8/1/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5069.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2552–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: ESM Const Agmt Castle Solar to be effective 7/30/2021.

Filed Date: 7/29/21.
Accession Number: 20210729–5072.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2553–000.
Applicants: Entergy Texas, Inc.
Description: § 205(d) Rate Filing: ETI–ETEC Wholesale Distribution Service Agreement to be effective 8/1/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5092.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2554–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 5995; Queue No. AD2–160/AE2–253 to be effective 3/3/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5093.
Comments Due: 5 p.m. ET 8/19/21.

Docket Numbers: ER21–2555–000.
Applicants: Martinsville OnSite Generation, LLC.
Description: Baseline eTariff Filing: MBR Tariff Authority to be effective 10/1/2021.
Filed Date: 7/29/21.
Accession Number: 20210729–5098.
Comments Due: 5 p.m. ET 8/19/21.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF21–1095–000.
Applicants: Generate Colchester Fuel Cells, LLC.
Description: Form 556 of Generate Colchester Fuel Cells, LLC.
Filed Date: 7/29/21.
Accession Number: 20210729–5042.
Comments Due: 5 p.m. ET 8/19/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by 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: July 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–16601 Filed 8–3–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Number: PR21–56–000.
Applicants: Public Service Company of Colorado.
Description: § 284.123(g) Rate Filing: Big Sandy Fuel Filing effective 9/1/2021 to be effective N/A.
Filed Date: 7/28/21.
Accession Number: 20210728–5071.
Comments Due: 5 p.m. ET 8/18/21.

Docket Numbers: RP21–978–000.
Applicants: Elba Express Company, L.L.C.
Description: § 4(d) Rate Filing: Interim Update of Fuel Retention Rates—2021 to be effective 9/1/2021.
Filed Date: 7/28/21.
Accession Number: 20210728–5016.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: RP21–979–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement Update (Conoco August 21) to be effective 8/1/2021.
Filed Date: 7/28/21.
Accession Number: 20210728–5027.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: RP21–980–000.
Applicants: Whiting Oil and Gas Corporation, Fundare Resources Operating Company, LLC.
Description: Request for Temporary Waiver and Expedited Action of Capacity Release Regulations, et al. of Whiting Oil and Gas Corporation, et al. under RP21–980.
Filed Date: 7/28/21.
Accession Number: 20210728–5029.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: RP21–981–000.
Applicants: Big Sandy Pipeline, LLC.
Description: Compliance filing Big Sandy Fuel Filing effective 9/1/2021 to be effective N/A.
Filed Date: 7/28/21.
Accession Number: 20210728–5064.
Comments Due: 5 p.m. ET 8/9/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by 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: July 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–16602 Filed 8–3–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–2533–000]

Bay Tree Lessee, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Bay Tree Lessee, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 18, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling

link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–16604 Filed 8–3–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–2532–000]

Bay Tree Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Bay Tree Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 18, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–16603 Filed 8–3–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–2535–000]

Dichotomy Power Maine, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Dichotomy Power Maine, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 18, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link.

Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–16605 Filed 8–3–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ21–10–000]

Oncor Electric Delivery Company LLC; Notice of Filing

Take notice that on July 29, 2021, Oncor Electric Delivery Company LLC submitted its tariff filing: Withdrawal of Oncor TFO Tariff Rate Changes, effective March 26, 2021.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on August 19, 2021.

Dated: July 29, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–16599 Filed 8–3–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[Petition IV–2019–7; FRL–8783–01–R4]

Clean Air Act Operating Permit Program; Petition for Objection to State Operating Permit for ABC Coke Plant (Jefferson County, Alabama); Notice of Final Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petition to object to state operating permit.

SUMMARY: On June 30, 2021, the Environmental Protection Agency (EPA) Administrator signed an Order denying a petition dated June 13, 2019 (the Petition) from Gasp (Petitioner). The Petition requested that EPA object to a Clean Air Act (CAA) title V operating permit issued to Drummond Coke for its ABC Coke Plant located in Jefferson County, Alabama. The title V operating permit was issued by the Jefferson County Department of Health (JCDH) with a final permit number 4–07–0001–04. The Order constitutes a final action on the Petition.

ADDRESSES: Copies of the Order, the Petition, and all pertinent information relating thereto are on file at the following location: U.S. EPA Region 4; Air and Radiation Division; 61 Forsyth Street SW; Atlanta, Georgia 30303–8960. The Order and Petition are also available electronically at the following addresses: *https://www.epa.gov/sites/production/files/2021-07/documents/abc_coke_order_7-07-21.pdf*; *https://www.epa.gov/title-v-operating-permits/title-v-petition-database*.

FOR FURTHER INFORMATION CONTACT: Art Hofmeister, Air Permits Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. EPA, Region 4, 61 Forsyth Street SW, Atlanta, GA 30303–8960. The telephone number is (404) 562–9115. Mr. Hofmeister can also be reached via electronic mail at *hofmeister.art@epa.gov.*

SUPPLEMENTARY INFORMATION: The Clean Air Act (CAA) affords EPA a 45-day period to review and, as appropriate, the authority to object to operating permits proposed by state permitting authorities under title V of the CAA, 42 U.S.C. 7661–7661f. Section 505(b)(2) of the CAA and 40 CFR 70.8(d) authorize any person to petition the EPA Administrator to object to a title V operating permit within 60 days after the expiration of EPA's 45-day review period if EPA has not objected on its own initiative. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or the grounds for the issues arose after this period.

Petitioner submitted a petition requesting that EPA object to the CAA title V operating permit no. 4–07–0001–04 issued by JCDH to the ABC Coke Plant. Petitioner requested that the Administrator object to the permit for the following reasons: The permit omitted applicable requirements, including requirements related to total annual benzene; the permit failed to include adequate monitoring to ensure compliance with applicable requirements; and the permit application was inadequate or incomplete.

On June 30, 2021, the Administrator issued an Order denying the Petition. The Order explains EPA's basis for denying the Petition. Pursuant to sections 307(b) and 505(b)(2) of the CAA, a petition for judicial review of those parts of the Order that deny issues in the Petition may be filed in the United States Court of Appeals for the appropriate circuit within 60 days from the date this notice is published in the **Federal Register**.

Dated: July 27, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

[FR Doc. 2021–16612 Filed 8–3–21; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–8749–01–R10]

Clean Air Act Operating Permit Program; Petition for Objection to State Operating Permit for the Owens-Brockway Glass Container Inc. Facility, Multnomah County, Oregon

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final Order on Petition for objection to Clean Air Act title V operating permit.

SUMMARY: The Environmental Protection Agency (EPA) Administrator signed an Order, dated May 10, 2021, granting in part and denying in part a petition dated February 4, 2020, filed by EarthJustice, on behalf of Cully Air Action Team, Portland Clean Air, Oregon Environmental Council, and Verde. The Petition requested that the EPA object to a final operating permit No. 26–1876–TV–01 issued by the Oregon Department of Environmental Quality (ODEQ) to the Owens Brockway Glass Container Inc. facility located in Portland, Oregon.

ADDRESSES: The Petition (without attachments) and final Order are available electronically at: *https://www.epa.gov/title-v-operating-permits/title-v-petition-database.* Out of an abundance of caution for members of the public and our staff, the EPA Region 10 office is closed to the public to reduce the risk of transmitting COVID–19. Please contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view copies of the Petition, Order, and other supporting information.

FOR FURTHER INFORMATION CONTACT: Doug Hardesty at (208) 378–5759, or *hardesty.doug@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, it is intended to refer to the EPA.

The CAA affords the EPA a 45-day period to review and object to a title V operating permit proposed by a state permitting authority under title V of the CAA if the EPA determines the permit does not comply with the Act. Section 505(b)(2) of the CAA authorizes any person to petition the EPA Administrator to object to a title V operating permit within 60 days after the expiration of the EPA's 45-day review period if the EPA has not objected on its own initiative. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or unless the grounds for the issue arose after this period.

The EPA received the Petition from Earthjustice on behalf of Cully Air Action Team, Portland Clean Air, Oregon Environmental Council, and Verde, dated February 4, 2020, requesting that the EPA object to the issuance of title V operating permit no. 26–1876–TV–01 for the Owens-Brockway Glass Container Inc.'s Portland, Oregon facility.

The Petition claims that: (A) The final permit lacks conditions sufficient to assure compliance with the applicable particulate matter emission limit in the New Source Performance Standard for Glass Manufacturing (40 CFR part 60, subpart CC); (B) the final permit lacks sufficient monitoring, recordkeeping, and reporting to assure compliance with the applicable particulate matter emission limit in Oregon's Clean Air Act state implementation plan; (C) the final permit lacks conditions sufficient to assure compliance with the requirement to take ''reasonable precautions'' to control fugitive dust; (D) the final permit fails to assure compliance with the applicable chromium emission limit under 40 CFR part 63, subpart SSSSSS; (E) the final permit fails to assure compliance with the facility's general duty to prevent accidental releases under Clean Air Act section 112(r)(1); (F) that the final permit fails to assure compliance with the Plant Site Emissions Limits (PSELs) for lead (Pb) and sulfur dioxide (SO_2); and (G) the final permit unlawfully omits an enforceable compliance schedule to bring Owens-Brockway into compliance with applicable opacity and particulate matter limits.

On May 10, 2021, the EPA Administrator issued an Order granting claims A, B, and G and denying the remaining claims in the Petition. The Order explains the basis for the EPA's decision.

Sections 307(b) and 505(b)(2) of the CAA provide that the Order is subject to judicial review for those portions of the Order that deny issues raised in a petition. Any petition for review shall be filed in the United States Court of Appeals for the appropriate circuit no later than October 4, 2021.

Dated: July 27, 2021.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

[FR Doc. 2021–16647 Filed 8–3–21; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice: 2021–3016]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

DATES: Comments must be received on or before September 3, 2021 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* or by mail to Donna Schneider, Export-Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571. The information collection tool can be reviewed at: *https://www.exim.gov/sites/default/files/pub/pending/eib10-05.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please Donna Schneider, 202–565–3612.

SUPPLEMENTARY INFORMATION: Pursuant to the Export-Import Bank Act of 1945, as amended (12 U.S.C. 635, *et seq.*), the Export-Import Bank of the United States (EXIM), facilitates the finance of the export of U.S. goods and services by providing insurance or guarantees to U.S. exporters or lenders financing U.S. exports. By neutralizing the effect of export credit insurance or guarantees offered by foreign governments and by absorbing credit risks that the private sector will not accept, EXIM enables U.S. exporters to compete fairly in foreign markets on the basis of price and product. In the event that a borrower defaults on a transaction insured or guaranteed by EXIM, the insured or guaranteed exporter or lender may seek payment from EXIM by the submission of a claim.

Title and Form Number: EIB 10–05 Notice of Claim and Proof of Loss, Medium Term Guarantee.

OMB Number: 3048–0034.

Type of Review: Regular.

Need and Use: This collection of information is necessary, pursuant to 12 U.S.C. 635(a)(1), to determine if such claim complies with the terms and conditions of the relevant guarantee.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 65.

Estimated Time per Respondent: 1½ hours.

Annual Burden Hours: 97.5 hours.

Frequency of Reporting of Use: As needed to request a claim payment.

Government Expenses:

Reviewing time per year: 65 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $2,762 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $3,315.

Bassam Doughman,

IT Specialist.

[FR Doc. 2021–16568 Filed 8–3–21; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2021–3015]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

DATES: Comments must be received on or before September 3, 2021 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* or by mail to Donna Schneider, Export-Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571. Form can be viewed at *https://www.exim.gov/sites/default/files/pub/pending/eib10_03-1.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please Donna Schneider. 202–565–3612.

SUPPLEMENTARY INFORMATION: This collection of information is necessary, pursuant to 12 U.S.C. 635(a)(1), to determine eligibility of the export sales for insurance coverage. The Report of Premiums Payable for Financial Institutions Only is used to determine the eligibility of the shipment(s) and to calculate the premium due to Ex-Im Bank for its support of the shipment(s) under its insurance program. Export-Import Bank customers will be able to submit this form on paper or electronically.

By neutralizing the effect of export credit support offered by foreign governments and by absorbing credit risks that the private sector will not accept, EXIM enables U.S. exporters to compete fairly in foreign markets on the basis of price and product. Under the Working Capital Guarantee Program, EXIM provides repayment guarantees to lenders on secured, short-term working capital loans made to qualified exporters. The guarantee may be approved for a single loan or a revolving line of credit. In the event that a buyer defaults on a transaction insured by EXIM the insured exporter or lender may seek payment by the submission of a claim.

Title and Form Number: EIB 10–03 Notice of Claim and Proof of Loss, Export Credit Insurance Policies.

OMB Number: 3048–0033.

Type of Review: Regular.

Need and Use: This collection of information is necessary, pursuant to 12 U.S.C. 635(a)(1), to determine if such claim complies with the terms and conditions of the relevant insurance policy.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 300.

Estimated Time per Respondent: 60 minutes.

Annual Burden Hours: 300 hours.

Frequency of Reporting or Use: As needed to request claim payment.

Government Expenses:

Reviewing Time per Year: 300 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $12,750.

Benefits and Overhead: 20%.

Total Government Cost: $15,300.

Bassam Doughman,

IT Specialist.

[FR Doc. 2021–16569 Filed 8–3–21; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2021–3017]

Agency Information Collection Activities: Final Collection; Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

DATES: Comments should be received on or before September 3, 2021 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* or by mail to Donna Schneider, Export-Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571. The form can be viewed at: *https://www.exim.gov/sites/default/files/pub/pending/eib11-04.pdf.*

FOR FURTHER INFORMATION CONTACT: To request additional information, please Donna Schneider: 202–565–3612.

SUPPLEMENTARY INFORMATION: This collection of information is necessary, pursuant to 12 U.S.C. 635(a)(1), to determine eligibility of the export sales for insurance coverage. The Report of Premiums Payable for Financial Institutions Only is used to determine the eligibility of the shipment(s) and to calculate the premium due to Ex-Im Bank for its support of the shipment(s) under its insurance program. Export-Import Bank customers will be able to submit this form on paper or electronically.

This form will enable EXIM to identify the specific details of the proposed co-financing transaction between a U.S. exporter, EXIM, and a foreign export credit agency; the information collected includes vital facts such as the amount of U.S.-made content in the export, the amount of financing requested from EXIM, and the proposed financing amount from the foreign export credit agency. These details are necessary for approving this unique transaction structure and coordinating our support with that of the foreign export credit agency to ultimately complete the transaction and support U.S. exports—and U.S. jobs.

Titles and Form Number: EIB11–04, Co-Financing with Foreign Export Credit Agency.

OMB Number: 3048–0037.

Type of Review: Regular.

Need and Use: The information collected will provide information needed to determine compliance and creditworthiness for transaction requests submitted to the Export Import

Bank under its insurance, guarantee, and direct loan programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 60.

Estimated Time per Respondent: 15 minutes.

Annual Burden Hours: 15 hours.

Frequency of Reporting or Use: As needed.

Government Expenses:

Reviewing Time per Year: 15 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $637.50 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $765.

Bassam Doughman,

IT Specialist.

[FR Doc. 2021–16576 Filed 8–3–21; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0999; FR ID 41410]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it can further reduce the information collection burden for small business concerns with fewer than 25 employees.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before September 3, 2021.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control No.: 3060–0999.

Title: Hearing Aid Compatibility Status Report and Section 20.19, Hearing Aid-Compatible Mobile Handsets (Hearing Aid Compatibility Act).

Form Numbers: FCC Form 655 and FCC Form 855.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 934 respondents; 934 responses.

Estimated Time per Response: 13.9710921 hours per response (average).

Frequency of Response: On occasion and annual reporting requirements, recordkeeping requirements, and third-party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 157, 160, 201, 202, 214, 301, 303, 308, 309(j), 310 and 610 of the Communications Act of 1934, as amended.

Total Annual Burden: 13,049 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Information requested in the reports and certifications may include confidential information. However, covered entities are allowed to request that such materials submitted to the Commission be withheld from public inspection.

Needs and Uses: The Commission will submit the revised information collection to OMB to obtain a full three-year clearance. The changes being made to the information collect concern the Commission's wireless hearing aid compatibility rules as they relate to the obligations of wireless handset manufacturers and wireless service providers to: (1) Label and disclose certain information related to handset packaging; (2) post certain information on their publicly accessible websites; and (3) file annual status reports and certifications. No changes are being made to the information collection as related to standards development and the approved number of estimated respondents and responses.

The revisions to the information collection are necessitated by a Report and Order in WT Docket No. 20–3, FCC 21–28, adopted on February 16, 2021. In this Report and Order, the Commission adopted a new technical standard for determining hearing aid compatibility

between hearing aids and wireless handsets and made other corresponding and implementation changes. In addition, the Commission revised the information that handset manufacturers and service providers must include on hearing aid-compatible wireless handset package labels and in the related package inserts or user manuals. The Commission revised the labeling rule in order to streamline the rule and remove outdated requirements. The new rule requires that the package label provide the volume control capabilities of a hearing aid-compatible handset that meets volume control requirements, and it maintains the requirement that a hearing aid-compatible handset's package label state that the handset is hearing aid-compatible. The new rule still requires hearing aid-compatible handsets to list the handset's hearing aid-compatible rating, but moves the location in which it is required to be listed from the package label to the package insert or user manual. The other requirements for package inserts and user manuals have not changed, but the requirements have been reorganized to make them easier to follow. The Commission's labeling revisions continue to allow consumers to access the information that they need to understand the hearing aid compatibility of handsets they are considering for purchase. At the same time, the labeling revisions give handset manufacturers and service providers flexibility in designing package labels and conveying supplemental information.

The Report and Order also revised website posting requirements for handset manufacturers and service providers. The revised rule requires handset manufacturers and service providers to post to their publicly accessible websites the technical standard used to determine hearing aid compatibility in addition to the information that handset manufacturers and service providers are presently required to post. Since handset manufacturers and service providers are already required to include the technical standard used to determine hearing aid compatibility in package inserts or user manuals for hearing aid-compatible handsets, this change will not substantially impact the existing paperwork burden estimates that OMB has already approved for this information collection. Further, the website posting requirement has been revised to eliminate the requirement that service providers post to their publicly accessible websites the different levels of functionality of the hearing aid-compatible handsets that they offer to the public. This change offsets any burden added by the requirement that service providers post the technical standard used to determine hearing aid compatibility.

Finally, the Report and Order addressed the status reporting and certification requirements for handset manufacturers and service providers. The Report and Order revised the dates that service providers must file their FCC Form 855 certifications and handset manufacturers must file their FCC Form 655 status reports. The forms were due January 15 and July 15 each year, respectfully, and now are due by January 31 and July 31. These changes were made to accommodate Federal holidays at the start of January and July and to make sure the forms contain information for the full preceding 12-month periods. The Commission uses these forms as the principal way to ensure compliance with its wireless hearing aid compatibility requirements. The Commission is also revising the forms to reflect the Commission's current hearing aid compatibility de minimis provisions and to reflect the Commission's new mailing address.

The changes the Commission is making will not affect the number of respondents or responses, burden hours, or costs presently approved by OMB for this information collection. The Commission requests that OMB approve the proposed revisions to the currently approved information collection in order to implement the changes the Commission adopted in the Report and Order. These changes benefit handset manufacturers and service providers by reducing regulatory burden while continuing to ensure that the Commission can fulfill its statutory obligation to monitor compliance with its hearing aid compatibility rules and make more complete and accessible information available to consumers. All other paperwork burden requirements previously approved by OMB for this information collection remain unchanged.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–16636 Filed 8–3–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**. Copies of agreements are 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.: 201366.

Agreement Name: Hoegh Autoliners/Wallenius Wilhelmsen Ocean/EUKOR Car Carriers Space Charter Agreement.

Parties: Hoegh Autoliners, Inc.; Wallenius Wilhelmsen Ocean AS; and EUKOR Car Carriers, Inc.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The Agreement authorizes Hoegh and WWO/EUKOR to charter space to and from each other in all U.S. trades.

Proposed Effective Date: 9/6/2021.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/48502.

Dated: July 30, 2021.

Rachel E. Dickon,

Secretary.

[FR Doc. 2021–16596 Filed 8–3–21; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's

Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than September 3, 2021.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *First Bancorp of Taylorville, Inc., Taylorville, Illinois;* to merge with Mackinaw Valley Financial Services, Inc., and thereby indirectly acquire First Security Bank, both of Mackinaw, Illinois.

B. Federal Reserve Bank of St. Louis (Holly A. Rieser, Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *Pine Knob Holdings, LLC, Bowling Green, Kentucky;* to become a bank holding company by acquiring the following: 48.14 percent of the voting shares of First Cecilian Bancorp, Inc., and thereby indirectly acquiring The Cecilian Bank, both of Cecilia, Kentucky; 35.52 percent of the voting shares of Albany Bancorp, Inc., Albany, Kentucky, and thereby indirectly acquiring First & Farmers National Bank, Inc., Somerset, Kentucky; and 16.36 percent of the voting shares of Jackson Financial Corporation, and thereby indirectly acquiring FNB Bank, Inc., both of Mayfield, Kentucky.

Board of Governors of the Federal Reserve System, July 30, 2021.

Ann Misback,

Secretary of the Board.

[FR Doc. 2021–16631 Filed 8–3–21; 8:45 am]

BILLING CODE 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 (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 applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 19, 2021.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Allan C. Minnerath, individually, and as trustee of the Scott A. Minnerath Sauk Centre Trust under the James J. Minnerath Revocable Trust under agreement dated November 8, 2012, as amended; the Rachel K. Minnerath Sauk Centre Trust under the James J. Minnerath Revocable Trust under agreement dated November 8, 2012, as amended; and the Ryan J. Minnerath Sauk Centre Trust under the James J. Minnerath Revocable Trust under agreement dated November 8, 2012, as amended, and John A. Minnerath, as co-trustee of all trusts and all of Alexandria, Minnesota; and Mark W. Greiner, as co-trustee of all trusts, Tonka Bay, Minnesota;* to retain additional voting shares of Sauk Centre Financial Services, Inc., and thereby indirectly retain voting shares of Minnesota National Bank, both of Sauk Centre, Minnesota.

Board of Governors of the Federal Reserve System, July 21, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–16633 Filed 8–3–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)–PAR 18–812, NIOSH Member Conflict Review.

Date: October 26, 2021.

Time: 1:00 p.m.–3:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26506, Telephone: (304) 285–5951, *MGoldcamp@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–16610 Filed 8–3–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0405]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) 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: Submit written comments (including recommendations) on the collection of information by September 3, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review-Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0432. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Medical Device Recall Authority—21 CFR Part 810

OMB Control Number 0910–0432—Extension

This collection of information implements section 518(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360h(e)) and part 810 (21 CFR part 810), mandatory medical device recall authority provisions. Section 518(e) of the FD&C Act provides FDA with the authority to issue an order requiring an appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious, adverse health consequences or death, to: (1) Immediately cease distribution of such device and (2) immediately notify health professionals and device-user facilities of the order and to instruct such professionals and facilities to cease use of such device.

FDA will then provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be amended to require a mandatory recall of the device. If, after providing the opportunity for an informal hearing, FDA determines that such an order is necessary, the Agency may amend the order to require a mandatory recall.

FDA issued part 810 to implement the provisions of section 518 of the FD&C Act. The information collected under the mandatory recall authority provisions will be used by FDA to implement mandatory recalls.

In the **Federal Register** of April 5, 2021 (86 FR 17610), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Collections Specified in the Order—810.10(d)	2	1	2	8	16
Request for Regulatory Hearing—810.11(a)	1	1	1	8	8
Written Request for Review—810.12(a) and (b)	1	1	1	8	8
Mandatory Recall Strategy—810.14	2	1	2	16	32
Periodic Status Reports—810.16(a) and (b)	2	12	24	40	960
Termination Request—810.17(a)	2	1	2	8	16
Total Hours					1,040

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Documentation of Notifications to Recipients—810.15(b)	2	1	2	8	16

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification to Recipients—810.15(a) through (c)	2	1	2	12	24
Notification to Recipients; Follow-up—810.15(d)	2	1	2	4	8
Notification of Consignees by Recipients—810.15(e)	10	1	10	1	10
Total					42

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates are based on FDA's experience with voluntary recalls under 21 CFR part 7. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily.

Section 810.10(d)—Collections Specified in the Order—(Reporting)—FDA may require the person named in the cease distribution and notification order to submit certain information to the Agency, *e.g.,* distribution information, progress reports.

Section 810.11(a)—Request for Regulatory Hearing—(Reporting)—A request for regulatory hearing regarding the cease distribution and notification order must be submitted in writing to FDA.

Section 810.12(a) and (b)—Written Request for Review—(Reporting)—In lieu of requesting a regulatory hearing under § 810.11, the person named in the cease distribution and notification order may submit a written request to FDA asking that the order be modified or vacated. A written request for review of a cease distribution and notification order shall identify each ground upon which the requestor relies in asking that the order be modified or vacated, address an appropriate cease distribution and notification strategy, and address whether the order should be amended to require a recall of the device that was the subject of the order and the actions required by such a recall order.

Section 810.14—Mandatory Recall Strategy—(Reporting)—The person named in the cease distribution and notification order or a mandatory recall order must develop and submit a strategy to FDA for complying with the order that is appropriate for the individual circumstances.

Section 810.15(a) through (c)—Notifications to Recipients—(Third-Party Disclosure)—The person named in a cease distribution and notification order or a mandatory recall order must promptly notify each health professional, user facility, consignee, or individual of the order.

Section 810.15(b)—Documentation of Notifications to Recipients—(Recordkeeping)—Telephone calls or other personal contacts may be made in addition to, but not as a substitute for, the verified written communication, and shall be documented in an appropriate manner.

Section 810.15(d)—Notification to Recipients; Followup—(Third-Party Disclosure)—The person named in the cease distribution and notification order or mandatory recall order shall ensure that followup communications are sent to all who fail to respond to the initial communication.

Section 810.15(e)—Notification of Consignees by Recipients—(Third-Party Disclosure)—Health professionals, device user facilities, and consignees should immediately notify their consignees of the order.

Section 810.16(a) and (b)—Periodic Status Reports—(Reporting)—The person named in a cease distribution and notification order or a mandatory recall order must submit periodic status reports to FDA to enable the Agency to assess the person's progress in complying with the order. The frequency of such reports and the Agency official to whom such reports must be submitted will be specified in the order.

Section 810.17(a)—Termination Request—(Reporting)—The person named in a cease distribution and notification order or a mandatory recall order may request termination of the order by submitting a written request to FDA. The person submitting a request must certify that he or she has complied in full with all the requirements of the order and shall include a copy of the most current status report submitted to the Agency.

Based on a review of the information collection since our last request for OMB approval, we have made no changes to the burden estimate.

Dated: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16635 Filed 8–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Health Center Program: COVID–19 Data Collection Tools, OMB No. 0906–0062—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than September 3, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Health Center Program: COVID–19 Data Collection Tools, OMB No. 0906–0062—Revision.

Abstract: This information collection request was previously approved by OMB on June 11, 2020, as an emergency clearance (OMB No.: 0906–0062). HRSA is currently undertaking the standard Paperwork Reduction Act process for normal OMB approval.

During the COVID–19 public health emergency, HRSA-supported health centers and Federally Qualified Health Center Look-Alikes (look-alikes) have played a key role in providing testing and care for those affected by the virus. HRSA has awarded billions of dollars in new funding to support health center awardees and look-alikes in the detection, prevention, diagnosis, and treatment of COVID–19. This funding has enabled health centers to maintain or increase their staffing levels, conduct training, provide COVID–19 treatment, and administer millions of tests for both existing and new patients. In addition, HRSA, in collaboration with the Centers for Disease Control and Prevention, launched the Health Center COVID–19 Vaccine program as part of an Administration initiative focused on health equity. This occurred in February 2021 to directly allocate COVID–19 vaccines to HRSA-supported health centers.

This ICR to support the implementation of COVID–19 relief funding and response activities includes forms previously submitted in the emergency information collection

request clearance: (1) Health Center COVID–19 Data Collection Survey Tool, (2) Addendum to COVID–19 Data Collection Survey Tool, and (3) the Health Center COVID–19 Vaccine Program Readiness Assessment Tool. This revised information collection request also includes two newly added forms: (1) Primary Care Association (PCA) COVID–19 Data Collection Survey Tool [1] and (2) the Health Center COVID–19 Vaccine Program Conditions of Participation Agreement.

A 60-day notice published in the **Federal Register** on April 23, 2021, vol. 86, No. 77; pp. 21756–57. There were no public comments.

Need and Proposed Use of the Information: HRSA uses the data collected to optimize COVID–19 testing and vaccination; track health center capacity and the impact of COVID–19 on operations, patients, and staff; and better understand training and technical assistance, funding, and other health center resource needs. The data allow HRSA to assess health center capacity prior to program enrollment, supporting successful vaccine allocation strategies, while providing HRSA with information on the effectiveness of vaccine distribution through this program. In addition, the data inform HRSA in resource allocation and technical assistance to health centers.

The readiness assessment supports HRSA's analysis of health center ability to successfully participate in the Health Center COVID–19 Vaccine Program. These data are critical to determine health center capacity to implement the vaccination program as well as comply with program requirements. These data are used to assess program readiness including:

- Ability to safely store the vaccine
- Availability of trained and credentialed staff and other staff capacity
- Reporting capacity
- Sufficient PPE
- Plan for vaccine transport

The health center weekly survey and addendum support HRSA's ability to monitor progress towards the development and delivery of COVID–19 prevention, preparedness, and/or response activities; and ensure appropriate vaccine administration as well as better understand training and technical assistance, funding, and other health center resource needs.

The Conditions of Participation Agreement governs all COVID–19 vaccination activities at all health center sites that receive COVID–19 vaccine through the HRSA Health Center COVID–19 Vaccine Program. Health Centers that sign the agreement agree to adhere to each of the stated requirements.

The PCA weekly survey increases information sharing between health centers, PCAs, and HRSA in order to better support COVID–19 emergency response efforts inclusive of testing and vaccination activities. Data collected from the survey tool is used to track and monitor issues/challenges to program implementation and assess the need for the delivery/dissemination of targeted training and technical assistance.

Likely Respondents: HRSA-supported health centers, look-alikes, and PCAs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. 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. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses to form per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Condition of Participation Agreement (one-time completion for vaccine program participants only).	1,467 (Total health centers, including look-alikes, in 2019).	1	1,467	.25	366.75
Readiness Assessment Tool (one-time completion for vaccine program participants only).	1,467 (Total health centers, including look-alikes, in 2019).	1	1,467	.50	733.50
Health Center COVID–19 Data Collection Survey Tool (weekly completion of existing 20 questions).	1,389 (Total health centers in 2019)	48	66,672	1.00	66,672.00
Addendum to COVID–19 Data Collection Survey Tool (weekly completion for vaccine program participants only).	1,389 (Total health centers in 2019)	48	66,672	.50	33,336.00
PCA COVID–19 Data Collection Survey Tool (bi-weekly completion of existing six questions).	52	6	312	.75	234.00
Total	5,764		136,590		101,342.25

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

[1] The bi-weekly COVID–19 PCA Survey Tool (comprised of six questions) is currently approved under the HHS Secretary's Public Health Emergency Authority to waive the requirements of the Paperwork Reduction Act during the Public Health Emergency for reporting on a voluntary basis.

technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–16591 Filed 8–3–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Amendment for the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA) and section 1111 of the Public Health Service (PHS) Act, HHS is hereby giving notice that the charter for the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has been amended to set the time period for appointment of members to a term of up to 4 years. The effective date of the amendment is July 30, 2021.

FOR FURTHER INFORMATION CONTACT: Mia Morrison (DFO), Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–2521; or *mmorrison@hrsa.gov.*

SUPPLEMENTARY INFORMATON: The ACHDNC provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning certain activities described in section 1111 of the PHS Act (42 U.S.C. 300b–10), as further described below. The ACHDNC is also governed by the provisions of the FACA, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The ACHDNC advises the Secretary of HHS about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having, or at risk for, heritable disorders. The ACHDNC will review and report regularly on newborn and childhood screening practices, recommend improvements in the national newborn and childhood screening programs, and fulfill responsibilities described in section 1111 of the PHS Act. In addition, the ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are considered evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the PHS Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

The filing date of the ACHDNC charter remains November 10, 2020. A copy of the ACHDNC charter is available on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* A copy of the charter also can 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 *http://www.facadatabase.gov/.*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–16618 Filed 8–3–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: National Health Service Corps Scholar/Students To Service Travel Worksheet, OMB No. 0915–0278—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 4, 2021.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: National Health Service Corps Scholar/Students to Service Travel Worksheet, OMB No. 0915–0278—Extension.

Abstract: Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program (SP) and the Students to Service (S2S) Loan Repayment Program (LRP) use the online Travel Request Worksheet to request and receive travel funds from the federal government to visit eligible NHSC sites to which they may be assigned in accordance with the Public Health Service Act, section 331(c)(1).

The travel approval process is initiated when an NHSC scholar or S2S participant notifies the NHSC of an impending interview at one or more NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar or S2S participant has successfully been matched to an approved practice site in accordance with the Public Health Service Act, section 331(c)(3). Upon receipt of a completed Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the scholar or S2S participant and the NHSC logistics contractor regarding travel arrangements and authorization of the funding for the site visit or relocation.

Need and Proposed Use of the Information: This information will facilitate NHSC scholar and S2S participants' receipt of federal travel funds that are used to visit high-need NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar or S2S participant has

successfully been matched to an approved practice site.

Likely Respondents: Clinicians participating in the NHSC SP and the S2S LRP.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. 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. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Travel Request Worksheet	300	2	600	.0667	40.02
Total	300		600		40.02

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–16597 Filed 8–3–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to clarify and expand the authority for certain Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under section VI of this Declaration.

DATES: This amendment is effective as of August 4, 2021.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202–260–0365, *paige.ezernack@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, § 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the former Secretary, Alex M. Azar II, declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration effective on April 26, 2020, July 25, 2020, October 23, 2020, January 21, 2021, April 21, 2021 and July 20, 2021.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause. (85 FR 35100, June 8, 2020). On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 52136, August 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary's Declaration and authorizations issued by the Department's Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under Section V of the Declaration; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be

situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's liability protections; made explicit that there are substantive federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the declaration in full. (85 FR 79190, December 9, 2020). On February 2, 2021, the Acting Secretary Norris Cochran amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 7872, February 2, 2021). On February 16, 2021, the Acting Secretary amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 9516, February 16, 2021) and on February 22, 2021, the Department filed a notice of correction to the February 2 and February 16 notices correcting effective dates stated in the Declaration, and correcting the description of qualified persons added by the February 16, 2021 amendment. (86 FR 10588, February 22, 2021). On March 11, 2021, the Acting Secretary amended the Declaration to add additional Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under the Declaration. (86 FR 14462 March 16, 2021).

Secretary Xavier Becerra now amends section V of the Declaration to revise subsections (d) and (f) to clarify that qualified pharmacy technicians are Qualified Persons covered by the Declaration, and to expand the scope of authority for qualified pharmacy technicians to administer seasonal influenza vaccines to adults within the state where they are authorized to practice and for interns to administer seasonal influenza vaccines to adults consistent with other terms and conditions of the Declaration.

Accordingly, subsection V(d) authorizes:

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy),[1] (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) seasonal influenza vaccine administered by qualified pharmacy technicians and interns that the ACIP recommends to persons aged 19 and older according to ACIP's standard immunization schedule; or (3) FDA authorized or FDA licensed COVID –19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns or technicians under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s);

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

iv. In the case of seasonal influenza vaccine administered by qualified pharmacy technicians and interns, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

v. In the case of pharmacy technicians, the supervising pharmacist must be readily and immediately available to the immunizing qualified pharmacy technician;

vi. The licensed pharmacist must have completed the immunization training that the licensing State requires for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

vii. The licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

viii. The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation;[2]

ix. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

x. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry),

[1] Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, ''State-licensed or registered intern'' (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. Similarly, states vary on licensure and registration requirements for pharmacy technicians. Some states require certain education, training, and/or certification for licensure or registration; others either have no prerequisites for licensure or registration or do not require licensure or registration at all. As used herein, to be a ''qualified pharmacy technician,'' pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a Certified Pharmacy Technician (CPhT) certification from either the Pharmacy Technician Certification Board or National Healthcareer Association. *See* Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020 at 2, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

[2] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;

xi. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and

xii. The licensed pharmacist, the licensed or registered pharmacy intern and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

Further, the initial phrase of subsection V(f) is revised to state authorize ''Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or a pharmacist or pharmacy intern as authorized under the section V(d) of this Declaration. . . .''

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a ''qualified person'' is a ''covered person.'' Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure. ''Qualified person'' includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) ''a person within a category of persons so identified in a declaration by the Secretary'' under subsection (b) of the PREP Act. 42 U.S.C. 247d–6d(i)(8)

By this amendment to the Declaration, the Secretary clarifies and expands the authorization for a category of persons who are qualified persons under section 247d–6d(i)(8)(B). First, the amendment clarifies that qualified pharmacy technicians are authorized to administer Childhood vaccinations and COVID–19 vaccinations that are Covered Countermeasures under section VI of this Declaration. The Department has authorized qualified pharmacy technicians to administer these vaccines under section V(a) of the Declaration through Guidance issued by the Assistant Secretary for Health.[3] This amendment adds qualified pharmacy technicians to section V(d) of the Declaration, to clarify that these healthcare professionals are authorized subject to the conditions stated in that subsection. In addition, the amendment expands the authorization for qualified pharmacy technicians and interns to administer seasonal influenza vaccines under the supervision of a pharmacist to persons aged 19 and older consistent with ACIP recommendations. The Secretary anticipates that there will be a need for the adult population to receive both COVID–19 and seasonal influenza vaccines throughout the 2021–2022 influenza season. Health risks may increase for individuals who contract seasonal influenza concurrently with COVID–19, thus expanding the scope of authorized vaccinators for seasonal influenza lessens the harm otherwise caused by COVID–19.

While influenza incidence was lower than anticipated last fall and winter, the same cannot be assumed for the 2021–2022 flu season, as states have largely lifted the community mitigation measures previously in place at the height of the COVID–19 pandemic. Seasonal influenza has the potential to inflict significant burden and strain on the U.S. healthcare system in its own right; and in conjunction with the ongoing COVID–19 pandemic, a spike in influenza cases could overwhelm healthcare providers. Like the vaccination against COVID–19, the vaccination against influenza requires many people to be vaccinated within a short period of time, potentially creating a surge on the system. Concern also remains regarding the emergence of SARS-CoV–2 variants and their potential to cause disease both among vaccinated and unvaccinated populations. It is yet to be determined if COVID–19 vaccine boosters will be recommended; however, if boosters become necessary, allowing pharmacy interns and technicians to administer both COVID–19 vaccines and influenza vaccines would allow states maximum flexibility in limiting potential impacts of both illnesses. ACIP also recently voted unanimously in favor of COVID–19 and influenza vaccine co-administration.[4] [5] Like COVID–19 vaccines, influenza vaccines are administered as intramuscular (IM) injections, and would require minimal, if any, additional training to administer, and would not place any undue training burden on providers.

As qualified persons, these qualified pharmacy technicians and interns will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration. Second, to the extent that any State law that would otherwise prohibit these healthcare professionals who are a ''qualified person'' from prescribing, dispensing, or administering COVID–19 vaccines or other Covered Countermeasures, such law is preempted. On May 19, 2020, the Office of the General Counsel issued an advisory opinion concluding that, because licensed pharmacists are ''qualified persons'' under this declaration, the PREP Act preempts state law that would otherwise prohibit such pharmacists from ordering and administering authorized COVID–19 diagnostic tests.[6] The opinion relied in part on the fact that the Congressional delegation of authority to the Secretary under the PREP Act to specify a class of persons, beyond those who are authorized to administer a covered countermeasure under State law, as ''qualified persons'' would be rendered a nullity in the absence of such preemption. This opinion is incorporated by reference into this declaration. Based on the reasoning set forth in the May 19, 2020 advisory opinion, any State law that would otherwise prohibit a member of any of the classes of ''qualified persons''

[3] Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited June 17, 2021).

[4] *https://www.medpagetoday.com/meetingcoverage/acip/93283.*

[5] *https://www.aappublications.org/news/2021/06/24/acip-flu-rabies-dengue-062421.*

[6] Department of Health and Human Services General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act, May 19, 2020, available at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf/* (last visited Jan. 24, 2021). *See also,* Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 12, 2021, available at: *https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf* (last visited Jan. 24, 2021).

specified in this declaration from administering a covered countermeasure is likewise preempted. In accordance with section 319F–3(i)(8)(A) of the Public Health Service Act, a State remains free to expand the universe of individuals authorized to administer covered countermeasures within its jurisdiction under State law.

The plain language of the PREP Act makes clear that there is preemption of state law as described above. Furthermore, preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID–19 as it will enable States to quickly expand the vaccination workforce with additional qualified healthcare professionals where State or local requirements might otherwise inhibit or delay allowing these healthcare professionals to participate in the COVID–19 countermeasure program.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

Section V of the March 10, 2020 Declaration under the PREP Act for medical countermeasures against COVID–19, as amended April 10, 2020, June 4, 2020, August 19, 2020, as amended and republished on December 3, 2020, and as amended on February 2, 2021, and as amended March 11, 2021, is further amended pursuant to section 319F–3(b)(4) of the PHS Act as described below. All other sections of the Declaration remain in effect as republished at 85 FR 79190 (December 9, 2020).

1. Covered Persons, section V, delete in full and replace with:

V. Covered Persons
42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. ''Order'' as used herein and in guidance issued by the Office of the Assistant Secretary for Health [7] means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required. In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration; [8]

(b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

(c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act;

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy),[9] (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) seasonal influenza vaccine administered by qualified pharmacy technicians and interns that the ACIP recommends to persons aged 19 and older according to ACIP's standard immunization schedule; or (3) FDA authorized or FDA licensed COVID –19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns or technicians under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s);

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

iv. In the case of seasonal influenza vaccine administered by qualified pharmacy technicians and interns, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

v. In the case of pharmacy technicians, the supervising pharmacist must be readily and immediately available to the immunizing qualified pharmacy technician;

vi. The licensed pharmacist must have completed the immunization training that the licensing State requires for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the

[7] *See* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021).

[8] *See, e.g.,* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for COVID–19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf* (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Jan. 24, 2021) (collectively, OASH PREP Act Authorizations). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

[9] Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, ''State-licensed or registered intern'' (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. Similarly, states vary on licensure and registration requirements for pharmacy technicians. Some states require certain education, training, and/or certification for licensure or registration; others either have no prerequisites for licensure or registration or do not require licensure or registration at all. As used herein, to be a ''qualified pharmacy technician,'' pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a Certified Pharmacy Technician (CPhT) certification from either the Pharmacy Technician Certification Board or National Healthcareer Association. *See* Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020 at 2, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

recognition and treatment of emergency reactions to vaccines;

vii. The licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

viii. The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation; [10]

ix. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

x. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;

xi. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and

xii. The licensed pharmacist, the licensed or registered pharmacy intern and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.[11] Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services;

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or a pharmacist or pharmacy intern as authorized under the section V(d) of this Declaration, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID–19 vaccination effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to: (i) Documentation of completion of the Centers for Disease Control and Prevention COVID–19 (CDC) Vaccine Training Modules [12] and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, who confirms competency of the healthcare provider in preparation and administration of the COVID–19 vaccine(s) to be administered;

(g) Any member of a uniformed service (including members of the National Guard in a Title 32 duty status) (hereafter in this paragraph ''service member'') or Federal government, employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government service members, employees, contractors, or volunteers are qualified persons if the following requirement is met: The executive department or agency by or for which the Federal service member, employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that service member, employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that service member, employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the public or otherwise would be more limited in scope than the activities such service member, employees, contractors, or volunteers are authorized to carry out under this declaration; and

(h) The following healthcare professionals and students in a healthcare profession training program subject to the requirements of this paragraph:

1. Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered;

2. Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;

3. Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental,

[10] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

[11] *See, e.g.,*Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Jan. 24, 2021).

[12] *See* COVID–19 Vaccine Training Modules, available at *https://www.cdc.gov/vaccines/covid-19/training.html.*

podiatry, optometry or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a currently practicing healthcare professional experienced in administering intramuscular injections who administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered;

Subject to the following requirements:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. Vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s);

iii. The healthcare professionals and students must have documentation of completion of the Centers for Disease Control and Prevention COVID–19 Vaccine Training Modules and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID–19 vaccines;

iv. The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering vaccinations is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID–19 vaccine(s) to be administered and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID–19 vaccines;

v. The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation; [13]

vi. The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and

vii. The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

2. Effective Time Period, section XII, delete in full and replace with:

Liability protections for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through the means of distribution identified in Section VII(a) of this Declaration, begin on March 27, 2020 and extend through October 1, 2024.

Liability protections for all other Covered Countermeasures identified in Section VI of this Declaration, through means of distribution identified in Section VII(a) of this Declaration, begin on February 4, 2020 and extend through October 1, 2024.

Liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as identified in Section VII(b) of this Declaration, begin with a Declaration of Emergency as that term is defined in Section VII (except that, with respect to qualified persons who order or administer a routine childhood vaccination that ACIP recommends to persons ages three through 18 according to ACIP's standard immunization schedule, liability protections began on August 24, 2020), and last through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

Liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration begin on December 9, 2020 and last through (a) the final day the Declaration of Emergency is in effect. or (b) October 1, 2024. whichever occurs first.

Liability protections for Qualified Persons under section V(d) of the Declaration who are qualified pharmacy technicians and interns to administer seasonal influenza vaccine to persons aged 19 and older begin on August 4, 2021.

Liability protections for Qualified Persons under section V(f) of the Declaration begin on February 2, 2021, and last through October 1, 2024.

Liability protections for Qualified Persons under section V(g) of the Declaration begin on February 16, 2021, and last through October 1, 2024.

Liability protections for Qualified Persons who are physicians, advanced practice registered nurses, registered nurses, or practical nurses under section V(h) of the Declaration begins on February 2, 2021 and last through October 1, 2024, with additional conditions effective as of March 11, 2021and liability protections for all other Qualified persons under section V(h) begins on March 11, 2021 and last through October 1, 2024.

Authority: 42 U.S.C. 247d–6d.

Dated: July 30, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–16681 Filed 8–2–21; 11:15 am]

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[13] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public via online meeting. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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: Fogarty International Center Advisory Board.

Date: September 9–10, 2021.

Closed: September 09, 2021, 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Fogarty International Center, National Institutes of Health, 31 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Open: September 10, 2021, 12:00 p.m. to 3:00 p.m.

Agenda: Update and discussion of current and planned Fogarty International Center activities.

Place: Fogarty International Center, National Institutes of Health, 31 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Meeting Access: https://www.fic.nih.gov/About/Advisory/Pages/default.aspx.

Contact Person: Kristen Weymouth, Executive Secretary, Fogarty International Center, National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892–7952, 301–496–1415, *kristen.weymouth@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.fic.nih.gov/About/Advisory/Pages/default.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: July 30, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–16607 Filed 8–3–21; 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; Fellowship: Cardiovascular and Respiratory Sciences Overflow.

Date: August 27, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, (301) 435–5575, *hamannkj@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: July 30, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–16609 Filed 8–3–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

The meeting will be held as a virtual meeting and is open to the public, as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of this 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 Advisory Council on Drug Abuse.

Date: September 15, 2021.

Closed: 11:00 a.m. to 12:15 p.m.

Agenda: To review and evaluate grant applications.

Open: 12:45 p.m. to 4:30 p.m.

Agenda: Presentations and other business of the Council.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan R.B. Weiss, Ph.D., Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, Three White Flint North, RM 09D08, 11601 Landsdown Street, Bethesda, MD 20852, 301–443–6480, *sweiss@nida.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.drugabuse.gov/NACDA/NACDAHome.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 29, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–16577 Filed 8–3–21; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below and held as a virtual meeting. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: August 31, 2021.

Time: 12:00 p.m.–3:15 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, NIH, Rockledge 1, 6705 Rockledge Dr., Bethesda, MD 20892 (Virtual Meeting).

Videocast link: https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council. Please note, the link to the videocast meeting will be posted within a week of the meeting date.

Date: September 1, 2021.

Time: 10:00 a.m.–12:00 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, NIH, Rockledge 1, 6705 Rockledge Dr., Bethesda, MD 20892 (Virtual Meeting).

Videocast link: https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council. Please note, the link to the videocast meeting will be posted within a week of the meeting date.

Date: September 1, 2021.

Time: 1:15 p.m.–2:30 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, NIH, Rockledge 1, 6705 Rockledge Dr., Bethesda, MD 20892 (Virtual Meeting).

Videocast link: https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council. Please note, the link to the videocast meeting will be posted within a week of the meeting date.

Contact Person: Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 206–Q, Bethesda, MD 20892, 301–827–5517, *moenl@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/nhlbac/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(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: July 29, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–16549 Filed 8–3–21; 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; Alzheimer's Disease Genomics.

Date: October 18, 2021.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *parsadaniana@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: July 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–16536 Filed 8–3–21; 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; Opportunities for Collaborative Research at the NIH Clinical Center (U01).

Date: August 13, 2021.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Raj K. Krishnaraju, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, Bethesda, MD 20892, 301–435–1047, *kkrishna@csr.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. 93.306, 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: July 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–16537 Filed 8–3–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 Drug Abuse Special Emphasis Panel; Exploiting Genome or Epigenome Editing to Functionally Validate Genes or Variants

Involved in Substance Use Disorders (R21/R33 Clinical Trial Not Allowed).

Date: September 23, 2021.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–4471, *ramadanir@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 30, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–16608 Filed 8–3–21; 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 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 on Aging Special Emphasis Panel; Role of FSH.

Date: August 30, 2021.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Nijaguna Prasad, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301–496–9667, *nijaguna.prasad@nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Frontotemporal Dementia: Genes, Images, and Emotions.

Date: September 2, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Rajasri Roy, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–6477, *rajasri.roy@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: July 29, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–16538 Filed 8–3–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0011]

Declaration of Free Entry for Returned American Products (CBP Form 3311)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted no later than October 4, 2021 to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0011 in the subject line and the agency name. Please use the following method to submit comments:

Email. Submit comments to: *CBP_PRA@cbp.dhs.gov.*

Due to COVID–19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) 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) 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) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions 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, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Declaration for Free Entry of Returned American Products (CBP Form 3311).

OMB Number: 1651–0011.

Form Number: CBP Form 3311.

Current Actions: Extension.

Type of Review: Extension (without change).

Affected Public: Businesses.

Abstract: CBP Form 3311, *Declaration for Free Entry of Returned American Products,* which is authorized by, among others, 19 CFR 10.1, 10.66, 10.67, 12.41, 123.4, and 143.23, is used to collect information from the importer or authorized agent in order to claim duty-free treatment for articles entered under certain provisions of Subchapter I of Chapter 98 of the Harmonized Tariff Schedule of the United States (HTSUS, *https://hts.usitc.gov/current*). The form serves as a declaration that the articles are: (1) The growth, production, and manufacture of the United States; (2) are returned to the United States without having been advanced in value or improved in condition while abroad; (3) the goods were not previously entered under a temporary importation under bond provision; and (4) drawback was never claimed and/or paid.

This collection of information applies to members of the importing public and trade community who seek to claim duty-free treatment based on compliance with the aforementioned requirements. These members of the public and trade community are familiar with import procedures and with CBP regulations. Obligation to respond to this information collection is required to obtain benefits.

Type of Information Collection: CBP Form 3311, Declaration for Free Entry of Returned American Products.

Estimated Number of Respondents: 12,000.

Estimated Number of Annual Responses per Respondent: 35.

Estimated Number of Total Annual Responses: 420,000.

Estimated Time per Response: 0.10 hours.

Estimated Total Annual Burden Hours: 42,000.

Dated: July 30, 2021.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2021–16606 Filed 8–3–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2695–21; DHS Docket No. USCIS-USCIS–2021–0014]

RIN 1615–ZB89

Extension of Initial Registration Periods for New Temporary Protected Status Applicants Under the Designations for Venezuela, Syria, and Burma; Correction to the Notice on the Designation of Venezuela for Temporary Protected Status and Implementation of Employment Authorization for Venezuelans Covered by Deferred Enforced Departure

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

ACTION: Notice of initial registration period extensions.

SUMMARY: Through this notice, the Department of Homeland Security (DHS) announces extensions of the initial registration periods from 180 days to 18 months for initial (new) applicants under the Temporary Protected Status (TPS) designations for Venezuela, Syria, and Burma. This notice also provides certain specific corrections to the **Federal Register** notice regarding Venezuela at 86 FR 13574 (Mar. 9, 2021).

DATES: DHS is extending the initial registration periods from 180 days to 18 months for applicants who do not currently have TPS under the TPS designations for Venezuela, Syria, and Burma, as specified in this notice.[1] This extension to 18 months is the same time period of the TPS designation itself, allowing an individual to apply as an initial applicant any time during the 18-month designation periods for these three countries. However, applicants should be aware that the ability to file a late initial TPS application may not be available during any potential subsequent extensions of these designations, so individuals desiring TPS should take action to apply during this 18-month initial registration period in order to ensure that they do not miss the opportunity to obtain TPS. These initial registration period extensions apply to the following **Federal Register** notices:

Designation of Venezuela for Temporary Protected Status and Implementation of Employment Authorization for Venezuelans Covered by Deferred Enforced Departure (86 FR 13574):[2] The 18-month registration period to apply for TPS now runs from March 9, 2021, through September 9, 2022. *See also* corrections to Venezuela notice below.

Extension and Redesignation of Syria for Temporary Protected Status (86 FR 14946): The 18-month registration period for initial applications under the redesignation of TPS for Syria now runs from March 19, 2021, through September 30, 2022.

Designation of Burma (Myanmar) for Temporary Protected Status (86 FR 28132): The 18-month registration period now runs from May 25, 2021, through November 25, 2022.

FOR FURTHER INFORMATION CONTACT:

- Andria Strano, Acting Chief, Humanitarian Affairs Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, by mail at 5900 Capital Gateway Drive, Camp Springs, MD 20746, or by phone at 800–375–5283.
- For further information on TPS, please visit the USCIS TPS web page at *www.uscis.gov/tps.*
- If you have additional questions about TPS, please visit *uscis.gov/tools.* Our online virtual assistant, Emma, can answer many of your questions and point you to additional information on our website. If you are unable to find your answers there, you may also call our U.S. Citizenship and Immigration Services (USCIS) Contact Center at 800–375–5283 (TTY 800–767–1833).
- Applicants seeking information about the status of their individual cases may check Case Status Online, available on the USCIS website at *www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).
- Further information will also be available at local USCIS offices upon publication of this notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

DHS—U.S. Department of Homeland Security
EAD—Employment Authorization Document
Form I–765—Application for Employment Authorization
Form I–821—Application for Temporary Protected Status
Government—U.S. Government

[1] The 60-day re-registration period (March 19, 2021, through May 18, 2021) for existing TPS beneficiaries under TPS Syria is not changing. *See* 86 FR 14946 (Mar. 19, 2021).

[2] A **Federal Register** notice was published on March 24, 2021, correcting defects in the original notice of Designation of Venezuela for Temporary Protected Status and Implementation of Employment Authorization for Venezuelans Covered by Deferred Enforced Departure. *See* 86 FR 15694. This notice provides further corrections.

INA—Immigration and Nationality Act
Secretary—Secretary of Homeland Security
TPS—Temporary Protected Status
TTY—Text Telephone
USCIS—U.S. Citizenship and Immigration Services

Background on Temporary Protected Status (TPS)

- TPS is a temporary immigration status granted to eligible nationals of a country designated for TPS under the Immigration and Nationality Act (INA) or to eligible persons without nationality who last habitually resided in the designated country.
- During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, are employment authorized, and may obtain Employment Authorization Documents (EADs), so long as they continue to meet the requirements of TPS.
- TPS beneficiaries may also apply for travel authorization as a matter of discretion.
- To qualify for TPS, beneficiaries must meet the eligibility standards at INA section 244(c)(1)–(2), 8 U.S.C. 1254a(c)(1)–(2).
- When the Secretary of Homeland Security (Secretary) terminates a country's TPS designation, beneficiaries return to one of the following:
  - The same immigration status or category that they maintained before TPS, if any (unless that status or category has since expired or been terminated); or
  - Any other lawfully obtained immigration status or category they received while registered for TPS, as long as it is still valid on the date TPS terminates.

Purpose of This Action

Through this **Federal Register** notice, DHS is extending the initial registration periods from 180 days to 18 months for initial applicants (that is, individuals who do not currently have TPS) under the TPS designations for Venezuela, Syria, and Burma, as specified in this notice. The initial registration periods will now run for the entire 18-month period of the TPS designations for Venezuela and Burma, and for the entire 18-month period of TPS redesignation for Syria. This will allow individuals to submit an initial application for TPS and an application for employment authorization documentation (if desired), during the relevant country's TPS designation or redesignation.

DHS is extending the registration period for a number of reasons. In general, individuals must be given an initial registration period of no less than 180 days to register for TPS, but the Secretary has discretion to provide for a longer registration period. See 8 U.S.C. 1254a(c)(1)(A)(iv). Historically, the length of the initial registration period has varied. *Compare* 66 FR 14214 (March 9, 2001) (18 months initial registration period for applicants under TPS designation for El Salvador) *with* 80 FR 36346 (June 24, 2015) (180-day initial registration period for applicants under TPS designation for Nepal). In recent years, this period has most typically been limited to the statutory minimum of 180 days, although later extensions of the initial registration period have also been announced for some countries. *See, e.g.,* 81 FR 4051 (Jan. 25, 2016) (setting 180-day initial registration period during extension and redesignation of South Sudan for TPS); 78 FR 1866 (Jan. 9, 2013) (setting 180-day initial registration period during extension and redesignation of Sudan for TPS); 75 FR 39957 (July 13, 2010) (extending previously announced initial 180-day registration period for Haiti TPS applicants to allow more time for individuals to apply). After reevaluating the initial 180-day registration periods announced for TPS under the new designations for Venezuela and Burma and the redesignation of Syria, DHS has determined that it will provide the full 18 months of these designations for applicants to file their initial Form I–821 and Form I–765 to obtain an EAD, if desired. Limiting the initial registration period to 180 days may place a burden on applicants who are unable to timely file but would otherwise be eligible for a grant of TPS. In addition, permitting registration throughout the entirety of the designation period could reduce the operational burden on USCIS, as incoming applications may be spread out over a longer period of time. This extended registration period is in keeping with the humanitarian purpose of TPS and will better advance the goal of ensuring ''the Federal Government eliminates . . . barriers that prevent immigrants from accessing government services available to them.'' *See Executive Order 14012, Restoring Faith in Our Legal Immigration Systems and Strengthening Integration and Inclusion Efforts for New Americans,* 86 FR 8277 (Feb. 5, 2021).

In addition, through this **Federal Register** notice, DHS is making corrections to the **Federal Register** notice regarding Venezuela's TPS designation that was published on March 9, 2021, at 86 FR 13574. USCIS is correcting the second paragraph of the section titled ''Required Application Forms and Application Fees To Register for TPS'' to correct the end date of the EAD validity period noted in that section from ''September 7, 2021'' to ''September 9, 2022.'' USCIS is also correcting the section titled ''Refiling a TPS Registration Application After Receiving a Denial of a Fee Waiver Request'' in order to remove erroneous references to a ''good cause'' exception to late filings for initial TPS applicants under the Venezuela designation.[3]

Corrections

In FR Doc. 2021–04951, beginning on page 13574, in the **Federal Register** of March 9, 2021, make the following corrections:

1. On page 13578, the sentence indicating ''Although not required to do so, if you want to obtain an EAD valid through September 7, 2021, you must file an Application for Employment Authorization (Form I–765) and pay the Form I–765 fee (or submit a Request for a Fee Waiver (Form I–912))'' is corrected to read as follows: ''Although not required to do so, if you want to obtain an EAD valid through September 9, 2022, you must file an Application for Employment Authorization (Form I–765) and pay the Form I–765 fee or request a fee waiver''.

2. On page 13578, the heading ''Refiling a TPS Registration Application After Receiving a Denial of a Fee Waiver Request'' is corrected to read as follows: ''Refiling a TPS Registration Application after Receiving Notice that USCIS Did Not Grant the Fee Waiver Request''.

3. On page 13578, the first paragraph under the heading that currently reads ''Refiling a TPS Registration Application After Receiving a Denial of a Fee Waiver Request'' is struck and replaced with the following correction:

''You should file as soon as possible so USCIS can process your application and issue an EAD promptly, if you requested one. If USCIS does not grant your fee waiver request related to your initial TPS application, you must refile your Form I–821 for TPS, along with the required fees, by September 9, 2022 to continue seeking initial TPS. If USCIS does not grant your fee waiver request, you may also refile your Form I–765, with fee, either with your Form I–821 or at a later time as long as it is within the period that Venezuela is designated for TPS. For more information on late

[3] *See* 8 CFR 244.2(f) and (g) (noting requirements for consideration of late initial TPS registration applications). A ''good cause'' exception to late filings is applicable only to persons re-registering for TPS as per INA § 244(c)(3)(C), not to initial registrants.

initial registration, visit the USCIS TPS web page at *uscis.gov/tps.*''

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2021–16611 Filed 8–3–21; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[XXXD5198NI DS61100000 DNINR0000.000000 DX61104]

Notice To Reopen the Exxon Valdez Oil Spill Public Advisory Committee Call for Nominations

AGENCY: Office of the Secretary, Interior.

ACTION: Notice to reopen a call for nominations.

SUMMARY: A request for nominations was published by the Department of the Interior in the **Federal Register** on April 29, 2021, for specific positions on the *Exxon Valdez* Oil Spill Public Advisory Committee (Committee). This Committee advises the Exxon Valdez Oil Spill Trustee Council (Trustee Council) on decisions related to the planning, evaluation, funds allocation, and conduct of injury assessment and restoration activities related to the T/V *Exxon Valdez* oil spill of March 1989.

DATES: The nomination period for the notice published on April 29, 2021, at 86 FR 22703, is reopened. Nominations for the vacant positions are due September 3, 2021.

ADDRESSES: A complete nomination package should be submitted by hard copy or via email to Shiway Wang, Acting Executive Director, *Exxon Valdez* Oil Spill Trustee Council, 4230 University Drive, Suite 220, Anchorage, Alaska, 99508–4650, or at *shiway.wang@alaska.gov.* Also please copy Linda Kilbourne, Administrative Manager, on any email correspondence at *linda.kilbourne@alaska.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Philip Johnson, Department of the Interior, Office of Environmental Policy and Compliance, telephone number: (907) 786–3914; email: *philip_johnson@ios.doi.gov.*

SUPPLEMENTARY INFORMATION: The Committee was created pursuant to Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska,* Civil Action No. A91–081 CV. The Committee advises the Trustee Council on matters relating to decisions on injury assessment, restoration activities, or other use of natural resource damage recoveries obtained by the government. The Trustee Council consists of representatives of the U.S. Department of the Interior, U.S. Department of Agriculture, National Oceanic and Atmospheric Administration, Alaska Department of Fish and Game, Alaska Department of Environmental Conservation, and Alaska Department of Law.

The Committee consists of 10 members to reflect balanced representation from each of the following principal interests: Aquaculture/mariculture, commercial tourism, conservation/environmental, recreation, subsistence use, commercial fishing, native landownership, sport hunting/fishing, science/technology, and public-at-large.

We are soliciting nominations for seven positions that represent aquaculture/mariculture, commercial fishing, commercial tourism, recreation, Native landownership, subsistence, and public-at-large interests. The Committee members will be selected and appointed by the Secretary of the Interior to serve a two-year term.

Nominations for membership may be submitted by any source. Nominations should include a résumé providing an adequate description of the nominee's qualifications, including information that would enable the Department of the Interior to make an informed decision regarding meeting the membership requirements of the Committee and permit the Department of the Interior to contact a potential member.

Authority: 5 U.S.C. appendix 2.

Philip Johnson,

Regional Environmental Officer, Office of Environmental Policy and Compliance.

[FR Doc. 2021–16571 Filed 8–3–21; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[XXXD5198NI DS61100000 DNINR0000.000000 DX61104]

Notice of Teleconference Meeting of the Exxon Valdez Oil Spill Public Advisory Committee

AGENCY: Office of the Secretary, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Department of the Interior, Office of the Secretary, is announcing that the *Exxon Valdez* Oil Spill (EVOS) Trustee Council's Public Advisory Committee (PAC) will meet by video teleconference as noted below.

DATES: The virtual meeting will be held on September 28–29, 2021, beginning at 9:30 a.m. to 12 p.m. and 2 to 4 p.m. Alaska Time (AKT) for both days.

ADDRESSES: The meeting will be virtual only using the Zoom meeting platform. To view a tutorial on how to join a Zoom meeting, please go to *https://support.zoom.us/hc/en-us/articles/201362193-How-Do-I-Join-A-Meeting-.* The video feature will be turned off for all attendees except for the EVOS PAC, Trustee Council staff, presenters, and speakers during public comment to limit bandwidth use and maximize connectivity during the meeting. Please remain muted until you are called upon to speak.

Connect to meeting using Zoom link (video and audio):

https://zoom.us/j/93034091186?pwd=MWNsVFdBNllveWhqSS8xUFhwTTdGQT09

Meeting ID: 930 3409 1186

Passcode: 672577

Follow the prompts; you will be asked if you would like to join audio with internet (your device microphone/speaker) or use a telephone (follow the prompts accordingly).

Connect to the meeting via telephone (audio only, no video):

Dial any of the following numbers:

(253) 215–8782
(669) 900–6833
(346) 248–7799
(312) 626–6799
(929) 205–6099
(301) 715–8592

Enter the Meeting ID 930 3409 1186#; there is no participant code, and use *6 to mute.

Please check the EVOS Trustee Council website for updates regarding the virtual meeting at *www.evostc.state.ak.us/.*

FOR FURTHER INFORMATION CONTACT: Dr. Philip Johnson, Department of the Interior, Office of Environmental Policy and Compliance, telephone number: (907) 786–3914; email: *philip_johnson@ios.doi.gov.*

SUPPLEMENTARY INFORMATION: The EVOS PAC was created pursuant to Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of*

America v. *State of Alaska,* Civil Action No. A91–081 CV.

The EVOS PAC meeting agenda will include the FY22 Work Plan. An opportunity for public comments will be provided. The final agenda and materials for the meeting will be posted on the EVOS Trustee Council website at *www.evostc.state.ak.us.* All EVOS PAC meetings are open to the public.

Public Input

Interested persons may choose to make oral comments at the meeting during the designated time. Depending on the number of people wishing to comment and the time available, the amount of time for oral comments may be limited. Interested parties should contact the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**) for advance placement on the public speaker list for this meeting.

Submitting Written Information or Questions

Interested members of the public may submit relevant information or questions for the Committee to consider during the public meeting. Written statements must be received by September 22, 2021, so that the information may be made available to the Committee for their consideration prior to this meeting. Written statements must be supplied to the Designated Federal Officer via email at *philip_johnson@ios.doi.gov.*

Public Disclosure of Comments

Before including your address, phone number, email address, or other personal identifying information in your comments, please 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 review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. appendix 2.

Philip Johnson,

Regional Environmental Officer, Office of Environmental Policy and Compliance.

[FR Doc. 2021–16570 Filed 8–3–21; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[21X.LLAK930100.L16100000.PN0000]

Notice of Intent To Prepare a Supplemental Environmental Impact Statement for the Coastal Plain Oil and Gas Leasing Program, Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In accordance with Secretary's Order 3401, *Comprehensive Analysis and Temporary Halt on all Activities in the Arctic National Wildlife Refuge Relating to the Coastal Plain Oil and Gas Leasing Program,* the Bureau of Land Management (BLM) Alaska State Office, Anchorage, Alaska, intends to prepare a Supplemental Environmental Impact Statement (EIS) to the September 2019 Coastal Plain Oil and Gas Leasing Program EIS. The Supplemental EIS will provide a comprehensive analysis of the potential environmental impacts of the Program, including by addressing the deficiencies identified in Secretary's Order 3401.

DATES: This Notice initiates the public scoping process for the Supplemental EIS. Comments on issues, impacts, and potential new alternatives to be analyzed may be submitted in writing until October 4, 2021. The BLM will announce on its website any additional venues for commenting during scoping.

ADDRESSES: You may submit comments by any of the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/102555/510.*
- *Mail:* BLM, Alaska State Office, Attention—Coastal Plain Supplemental EIS, 222 West 7th Avenue, #13, Anchorage, AK 99513–7599.

FOR FURTHER INFORMATION CONTACT: Serena Sweet, Project Lead, via email at *blm_ak_coastalplain_supplementalEIS@blm.gov,* or via telephone at 907–271–5960; or by mail at Bureau of Land Management, 222 West 7th Avenue, #13, Anchorage, Alaska 99513–7599. You may also request to be added to the mailing list for the Supplemental EIS. Additional background information and supporting documents may be found at the *https://eplanning.blm.gov/eplanning-ui/project/102555/510.*

Persons 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. FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The area comprising the Coastal Plain includes approximately 1.6 million acres within the approximately 19.3 million-acre Arctic National Wildlife Refuge. In September 2019 and in connection with Public Law 115–97, Dec. 22, 2017, the BLM completed the Coastal Plain Oil and Gas Leasing Final EIS. The BLM then issued a Record of Decision (ROD) for the Coastal Plain Oil and Gas Leasing Program on August 8, 2020 (85 FR 51754). The ROD approved a program to implement Section 20001 of Public Law 115–97, which directed the BLM to manage the oil and gas leasing program on the Coastal Plain in a manner similar to lease sales under the Naval Petroleum Reserves Production Act of 1976 (including regulations).

On June 1, 2021, the Secretary of the Interior issued Secretary's Order 3401, Section 4 of which directed ''a temporary halt on all Department activities related to the [Leasing] Program in the Arctic Refuge'' pending ''a new, comprehensive analysis of the potential environmental impacts of the Program'' to ''address . . . identified legal deficiencies.''

The purpose of this public scoping process is to determine the scope of issues to be addressed and to identify the significant issues, including any legal deficiencies in the Final EIS, related to an oil and gas leasing program within the Coastal Plain. Information received during this process will influence the development of the Supplemental EIS and guide the scope of the environmental 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 purpose and need of the Supplemental EIS is bound by statute and remains the same as for the September 2019 Final EIS, *i.e.,* to implement Section 20001 of Public Law 115–97. Potential new alternatives to be considered in the Supplemental EIS include, but are not limited to, those that would: Designate certain areas of the Coastal Plain as open or closed to leasing; permit less than 2,000 acres of surface development throughout the Coastal Plain; prohibit surface infrastructure in sensitive areas; and otherwise avoid or mitigate impacts from oil and gas activities.

The Supplemental EIS will evaluate impacts to various surface resources including, but not limited to, caribou, polar bears, birds, vegetation, and

surface waters including wetlands, as well as to other uses of the Coastal Plain, including subsistence uses. The Supplemental EIS will also consider impacts from greenhouse gas emissions from any Leasing Program.

After the scoping comment period is closed, the BLM will review and consider the scoping comments received and will develop a Draft Supplemental EIS, which BLM estimates will be completed approximately 6 to 8 months after the scoping period ends. At that time the Draft Supplemental EIS will be made available for public comment for at least 45 days. After the close of the Draft Supplemental EIS comment period, BLM will develop a Final Supplemental EIS incorporating comments received on the Draft, which BLM estimates will be completed approximately 6 months after the Draft Supplemental EIS comment period ends. A record of decision selecting a program alternative from the Final Supplemental EIS would be issued no sooner than 30 days after notice of the availability of the Final Supplemental EIS is published in the **Federal Register**.

Authority: 40 CFR 1501.9(d), 40 CFR 1501.7 (2019).

Laura Daniel-Davis,

Principal Deputy Assistant Secretary, Land and Minerals Management.

[FR Doc. 2021–16572 Filed 8–3–21; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR85672000, 21XR0680A2, RX.31480001.0040000; OMB Control Number 1006–0003]

Agency Information Collection Activities; Bureau of Reclamation Use Authorization Application

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Reclamation (Reclamation) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before October 4, 2021.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Jason Kirby, Bureau of Reclamation, P.O. Box 25007, Denver, CO 80225–0007; or by email to *jkirby@usbr.gov.* Please reference Office of Management and Budget (OMB) Control Number 1006–0003 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Jason Kirby by email at *jkirby@usbr.gov,* or by telephone at (303) 445–2895. Individuals who are hearing or speech impaired may call the Federal Relay Service at (800) 877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. 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.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, 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) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. 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 review, we cannot guarantee that we will be able to do so.

Abstract: Reclamation is responsible for approximately 6.5 million acres of land which directly support Reclamation's Federal water projects in the 17 Western States. Under Title 43 CFR part 429, individuals or entities wanting to use Reclamation's lands, facilities, or waterbodies must apply using Form 7–2540. Examples of such uses are:

—Agricultural uses such as grazing and farming;
—commercial or organized recreation and sporting activities;
—other commercial activities such as ''guiding and outfitting'' and ''filming and photography;'' and,
—resource exploration and extraction, including sand and gravel removal and timber harvesting.

We review applications to determine whether granting individual use authorizations are compatible with Reclamation's present or future uses of the lands, facilities, or waterbodies. When we find a proposed use compatible, we advise the applicant of the estimated administrative costs and estimated application processing time. In addition to the administrative costs, we require the applicant to pay a use fee based on a valuation or by competitive bidding. If the application is for construction of a bridge, building, or other significant construction project, Reclamation may require that all plans and specifications be signed and sealed by a licensed professional engineer.

Title of Collection: Bureau of Reclamation Use Authorization Application.

OMB Control Number: 1006–0003.

Form Number: Form 7–2540.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals, corporations, companies, and State and local entities who want to use Reclamation lands, facilities, or waterbodies.

Total Estimated Number of Annual Respondents: 225.

Total Estimated Number of Annual Responses: 225.

Estimated Completion Time per Response: 2 hours.

Total Estimated Number of Annual Burden Hours: 450 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Each time a use authorization is requested.

Total Estimated Annual Nonhour Burden Cost: $78,750.

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.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*).

Karen Knight,

Director, Dam Safety and Infrastructure.

[FR Doc. 2021–16583 Filed 8–3–21; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Smart Thermostats, Load Control Switches and Components Thereof, DN 3560*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Causam Enterprises, Inc. on July 28, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain smart thermostats, load control switches and components thereof. The complainant names as respondents: Alarm.com Holdings, Inc. of Tysons, VA; Alarm.com Inc. of Tysons, VA; Ecobee, Inc. of Canada; EnergyHub, Inc. of Brooklyn, NY; Itron, Inc. Liberty Lake, WA; Itron Distributed Energy Management, Inc. of Liberty Lake, WA; Resideo Smart Homes Technology (Tianjin) of China; Resideo Technologies, Inc. of Austin, TX; and Xylem Inc. of Rye Brook, NY. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3560'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: July 29, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–16552 Filed 8–3–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Radio Frequency Transmission Devices and Components Thereof, DN 3561;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov* . The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Zebra Technologies Corporation on July 29, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain radio frequency transmission devices and components thereof. The complainant names as respondents: OnAsset Intelligence, Inc. of Irving, TX. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3561'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures.[1]) Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: July 29, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–16551 Filed 8–3–21; 8:45 am]

BILLING CODE 7020–02–P

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0072]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Revision of a Currently Approved Collection; Explosives Employee Possessor Questionnaire—ATF Form 5400.28

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ) will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 days until September 3, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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;

—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;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—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) *The Title of the Form/Collection:* Explosives Employee Possessor Questionnaire.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number: ATF Form 5400.28.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households.

Other: Business or other for-profit.

Abstract: The Explosives Employee Possessor Questionnaire—ATF Form 5400.28 will be used to determine if an individual is qualified to serve as an employee possessor, who can ship, transport, receive, and/or possess materials for an explosives business or operation.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 10,000 respondents will use the form, and it will take each respondent 20 minutes to complete their responses.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 3,334 hours, which is equal to 10,000 (# of respondents) * .3333 (20 minutes).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3E.405A, Washington, DC 20530.

Dated: July 30, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–16594 Filed 8–3–21; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Antitrust Division

Granting of Requests for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**. The following transaction was granted early termination—on the date indicated—of the waiting period provided by law and the premerger notification rules. The listing includes the transaction number and the parties to the transaction. The Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice made the grants. Neither agency intends to take any action with respect to this proposed acquisitions during the applicable waiting period.

EARLY TERMINATION GRANTED

[07/29/2021]

20211133	G	Gray Television, Inc.; Quincy Media, Inc.

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division, Department of Justice.

[FR Doc. 2021–16651 Filed 8–3–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Clean Water Act

On July 27, 2021, the Department of Justice lodged a proposed Second Amended Consent Decree (''Second ACD'') in the United States District Court for the Eastern District of Kentucky, Louisville Division in the lawsuit entitled *Commonwealth of Kentucky and United States of America* v. *The Louisville and Jefferson County Metropolitan Sewer District (''MSD''),* Civil Action No. 3:05–cv–00236–CRS.

A Consent Decree resolving the Plaintiffs' Clean Water Act (''CWA'') claims against MSD was entered by the Court in 2005. That Consent Decree was amended and the Amended Consent Decree was entered by this Court in 2009. The proposed Second ACD includes significant new work to enable MSD to meet the objectives of the CWA. The proposed Second ACD replaces and supersedes the 2009 Amended Consent Decree.

Under the proposed Second ACD, MSD is required to undertake critical infrastructure projects to ensure that the goals of the Clean Water Act are met. As a result of the greater priority and expense of this new work, the proposed Second ACD extends the deadlines for the few remaining projects required by the 2009 Amended Consent Decree. The proposed work required under the Second ACD is estimated to cost approximately $1.1 billion. While the longest extension to one of the remaining projects is eleven years, most of the work will be completed much sooner.

The publication of this notice opens a period for public comment on the Second ACD. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to the *Commonwealth of Kentucky and United States of America* v. *The Louisville and Jefferson County Metropolitan Sewer District,* the D.J. Ref. No. 90–5–1–1–08254. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Amended Consent Decree may be examined and downloaded at this Justice Department website: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Second ACD upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $15.25 (25 cents per page reproduction cost) payable to the United States Treasury for the Second ACD.

Lori Jonas,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–16626 Filed 8–3–21; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On July 27, 2021, the Department of Justice filed a Complaint and simultaneously lodged a Consent Decree with the United States District Court for the Central District of California in *United States* v. *Advanced Flow Engineering, Inc.,* Civ. No. 5:21-cv-01249.

The proposed Consent Decree settles claims brought by the United States for violations of the Clean Air Act arising from Defendant's manufacture and sale of motor vehicle parts that bypass, defeat, and/or render inoperative the vehicle's installed emission controls, commonly known as ''defeat devices.'' *See* 42 U.S.C. 7522(a)(3)(B). The Consent Decree resolves these claims and prohibits Defendant from: (1) Manufacturing, selling or installing defeat devices; (2) providing technical support for defeat devices; (3) transferring intellectual property for defeat devices; and (4) owning any interest in any person or entity that manufacturers, sells, offers to sell, or installs defeat devices or earning income from the distribution or installation of defeat devices. It also requires Defendant to pay a civil penalty of $250,000, which was based on its financial condition.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division and should refer to *United States* v. *Advanced Flow Engineering, Inc.* D.J. Ref. No. 90–5–2–1–12079. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $17.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Lori Jonas,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–16623 Filed 8–3–21; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Methylene Chloride Standard

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety and Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 3, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie by telephone at 202–693–0456 or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The standard requires employers to monitor employee exposure to methylene chloride (MC), to provide medical consultation and examinations, to train employees about the hazards of MC in their working areas, and to establish and maintain records of employee exposure to MC. These records will be used by employers, employees, physicians and the Government to ensure that employees are not being harmed by exposure to MC. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on April 29, 2021 (86 FR 22715).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: Methylene Chloride Standard.

OMB Control Number: 1218–0179.

Affected Public: Private Sector: Businesses or other for-profits.

Total Estimated Number of Respondents: 84,595.

Total Estimated Number of Responses: 236,458.

Total Estimated Annual Time Burden: 61,813 hours.

Total Estimated Annual Other Costs Burden: $21,048,881.30.

Authority: 44 U.S.C. 3507(a)(1)(D).

Crystal Rennie,

Senior PRA Analyst.

[FR Doc. 2021–16580 Filed 8–3–21; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Slings Standard

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety and Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 3, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie by telephone at 202–693–0456 or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The provisions of the standard require that the employer make a periodic inspection of alloy steel chain slings at least once a year and to make and maintain a record of the inspection. It also requires the employer to ensure that each new, repaired or reconditioned alloy steel chain sling is proof tested and a certification record maintained. In addition, the standard requires the employer to maintain a record of the proof test on wire rope slings. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on April 27, 2021 (86 FR 22278).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: Slings Standard.

OMB Control Number: 1218–0223.

Affected Public: Private Sector: Businesses or other for-profits.

Total Estimated Number of Respondents: 381,502.

Total Estimated Number of Responses: 381,582.

Total Estimated Annual Time Burden: 31,398 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Crystal Rennie,

Senior PRA Analyst.

[FR Doc. 2021–16579 Filed 8–3–21; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (21–050)]

Notice of Intent To Grant an Exclusive, Co-Exclusive or Partially Exclusive Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant exclusive, co-exclusive or partially exclusive patent license.

SUMMARY: NASA hereby gives notice of its intent to grant an exclusive, co-exclusive or partially exclusive patent license to practice the inventions described and claimed in the patents and/or patent applications listed in **SUPPLEMENTARY INFORMATION** below.

DATES: The prospective exclusive, co-exclusive or partially exclusive license may be granted unless NASA receives written objections including evidence and argument, no later than August 19, 2021 that establish that the grant of the license would not be consistent with the requirements regarding the licensing of federally owned inventions as set forth in the Bayh-Dole Act and implementing regulations. Competing applications completed and received by NASA no later than August 19, 2021 will also be treated as objections to the grant of the contemplated exclusive, co-exclusive or partially exclusive license. Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act.

ADDRESSES: *Objections and Further Information:* Written objections relating to the prospective license or requests for further information may be submitted to Agency Counsel for Intellectual Property, NASA Headquarters at Email: *hq-patentoffice@mail.nasa.gov.* Questions may be directed to Phone: (202) 358–3437.

SUPPLEMENTARY INFORMATION: NASA intends to grant an exclusive, co-exclusive, or partially exclusive patent license in the United States to practice the inventions described and claimed in U.S. Patent Application Serial No. 16/104,824 entitled ''Cryogenic Flux Capacitor for Solid-State Storage and On-Demand Supply of Fluid Commodities,'' filed on August 17, 2018, to GenH2 Corporation, having its principal place of business in Titusville, Florida. The fields of use may be limited. NASA has not yet made a final determination to grant the requested license and may deny the requested license even if no objections are submitted within the comment period.

This notice of intent to grant an exclusive, co-exclusive or partially exclusive patent license is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective license will comply with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Information about other NASA inventions available for licensing can be found online at *http://technology.nasa.gov.*

Helen M. Galus,

Agency Counsel for Intellectual Property.

[FR Doc. 2021–16554 Filed 8–3–21; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; Computer and Information Science and Engineering Research Experiences for Undergraduates Past Participant Survey

AGENCY: National Science Foundation.

ACTION: Submission for OMB Review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register** and no comments were received. NSF is forwarding the proposed renewal submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAmain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays). Comments regarding this information collection are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling 703–292–7556.

NSF 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.

SUPPLEMENTARY INFORMATION:

Title of Collection: CISE REU Past Participant Survey—2021 Impact of REU Participation on Career Pathways.

OMB Approval Number: 3145–NEW.

Type of Request: Intent to establish an information collection.

Abstract: Every year the National Science Foundation (NSF) funds hundreds of Research Experience for Undergraduates (REU) activities through its REU program. The Directorate of Computer and Information Science and Engineering (CISE) is seeking to evaluate the effectiveness of the CISE REU program.

REUs provide undergraduate students at U.S. higher education institutions to work with a faculty on a research project. They can take the form of REU Sites or REU Supplements. REU Sites are based on independent proposals to initiate and conduct projects that engage a number of students in research, and REU Supplements are included as a component of proposals for new or renewal NSF grants or cooperative agreements or may be requested for ongoing NSF-funded research projects.

By offering this opportunity to undergraduate students the REU program seeks to expand student participation in all kinds of research—both disciplinary and interdisciplinary—encompassing efforts by individual investigators, groups, centers, national facilities, and others. It draws on the integration of research and education to attract a diverse pool of talented students into careers in science and engineering, including teaching and education research related to science and engineering, and to help ensure that these students receive the best education possible.

The data collection intends to assess the impact of REU participation on career pathways and will be done through an online survey. The researchers will collect data from past participants including the students and the mentors with a separate survey customized for each group. The specific evaluation objectives are:

1. Identify the career trajectory of the REU participants since their participation in the REU program including degrees they received, institutions they attended, and their current status (*e.g.,* employed, graduate students).

2. Document the structure of the REU experience that the respondents participated in. These may include the type of REU (*e.g.,* Site, Supplement), location of REU, and timing of REU.

3. Describe the REU mentors' perceptions of the REU program on the student participants and the mentors' career development.

4. Examine the skills the participants gained and experiences they had during their REU participation. These may include technical skills, information on graduate school application process, and research training.

5. Analyze the relationships between REU participation and career pathways specifically focusing on whether these experiences are associated with the participants' interest in and ultimate selection of research careers in computing.

Ultimately, the findings from the analysis of this data collection will be used to improve the impact of CISE REU Program in order to better reach its goals of providing meaningful research opportunities to undergraduate students and, in doing so, attracting a broad range of students to computing/STEM careers.

Use of information: The information collected through this survey will be used to evaluate the NSF CISE REU Program.

Expected Respondents: The survey will be sent to students and mentors who participated in the NSF CISE REU Program through an REU Site or a Supplement. Further, in order to obtain data from an appropriate comparison group, the researchers will also include participants of other REUs and similar activities. The CISE REU Program participant list will be obtained from NSF and comparison group participants will be culled from a list of individuals previously surveyed by the researchers. The estimated number of individuals who will be receiving this survey is 25,000. Based on an approximate response rate of 30%, there will be an estimated 7,500 respondents when the data collection is completed.

Average time per respondent: The online survey is designed to be completed in 20 minutes or less.

Frequency: Each respondent will be asked to complete this survey once during late summer/early fall 2021.

Estimated burden on public: Based on 7,500 estimated responses and 20 minutes per respondent, the estimate for this data collection is 2,500 burden hours.

Comments: Comments are invited on: (a) 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; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (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.

Dated: July 30, 2021.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2021–16638 Filed 8–3–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

National Artificial Intelligence Research Resource Task Force; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: National Artificial Intelligence Research Resource Task Force (84629) (Virtual).

Date and Time: August 30, 2021, 11:00 a.m. to 5:00 p.m. EDT.

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314; Virtual meeting.

To attend the virtual meeting, please send your request for the virtual meeting link to the following email: *cmessam@nsf.gov.*

Type of Meeting: Open.

Contact Person: Brenda Williams, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: 703–292–8900; email: *bwilliam@nsf.gov.*

Purpose Of Meeting: The Task Force shall investigate the feasibility and advisability of establishing and sustaining a National Artificial Intelligence Research Resource; and propose a roadmap detailing how such resource should be established and sustained.

Agenda: In this meeting, the Task Force will discuss (i) the goals, anticipated outcomes, and evaluation metrics of the National Artificial Intelligence Research Resource; (ii) ownership, administration, and governance models; and (iii) the range of computer capabilities that will form a key element of the resource.

Dated: July 30, 2021.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2021–16566 Filed 8–3–21; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–38679–LA; ASLBP No. 21–972–01–LA–BD01]

In the Matter of Cammenga and Associates, LLC ; Establishment of Atomic Safety and Licensing Board

Pursuant to delegation by the Commission, *see* 37 FR 28,710 (Dec. 29, 1972), and the Commission's regulations, *see, e.g.,* 10 CFR 2.103, 2.104, 2.105, 2.300, 2.309, 2.313, 2.318, 2.321, notice is hereby given that an Atomic Safety and Licensing Board (Board) is being established to preside over the following proceeding:

Cammenga and Associates, LLC

(Denial of License Amendment Requests)

This Board is being established pursuant to a filing titled ''Hearing Request'' submitted by Cammenga and Associates, LLC (Cammenga). The filing challenges the NRC Staff's decision in a July 1, 2021 letter denying Cammenga's request for amendments to License No. 21–26460–03E and Sealed Source and Device Registration Certificate NR–0210–D–101–E.

The Board is comprised of the following Administrative Judges:

Ronald M. Spritzer, Chairman, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Dr. Gary S. Arnold, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission Washington, DC 20555–0001.

Nicholas G. Trikouros, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission Washington, DC 20555–0001.

All correspondence, documents, and other materials shall be filed in accordance with the NRC E-Filing rule. *See* 10 CFR 2.302.

Rockville, Maryland.
Dated: July 29, 2021.

Edward R. Hawkens,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 2021–16543 Filed 8–3–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–223; NRC–2018–0053]

University of Massachusetts Lowell; University of Massachusetts Lowell Research Reactor

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering renewal of Facility Operating License No. R–125, held by the University of Massachusetts Lowell (UML, the licensee), which would authorize continued operation of the UML Research Reactor (UMLRR) at a maximum steady-state thermal power of 1.0 megawatt (MW). The UMLRR is a plate-type-fueled research reactor located on the campus of UML, in Lowell, Middlesex County, Massachusetts. If approved, the renewed license would authorize UML to continue to operate the UMLRR for an additional 20 years from the date of issuance of the renewed license. The NRC has prepared this environmental assessment (EA) and finding of no significant impact (FONSI) to consider the impacts associated with the renewal of the operating license.

DATES: The EA and FONSI referenced in this notice are available on August 4, 2021.

ADDRESSES: Please refer to Docket ID NRC–2018–0053 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 *https://www.regulations.gov* and search for Docket ID NRC–2018–0053. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://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.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of this notice.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 302–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Edward Helvenston, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–4067; email: *Edward.Helvenston@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering renewal of Facility Operating License No. R–125, which authorizes the licensee to operate the UMLRR, located on the campus of UML in Lowell, Middlesex County, Massachusetts, at a maximum steady-state thermal power of 1.0 MW. The renewed license would authorize continued operation of UMLRR for an additional 20 years from the date of issuance of the renewed license. UML submitted its renewal application by letter dated October 20, 2015. UML subsequently supplemented its renewal application as described under ''Identification of the Proposed Action'' in Section II of this notice. Therefore, as required by section 51.21 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Criteria for and identification of licensing and regulatory actions requiring environmental assessments,'' the NRC prepared this EA. Based on the results of the EA, the NRC did not identify any significant impacts from the proposed action (*i.e.,* license renewal) and is, therefore, issuing a FONSI in accordance with 10 CFR 51.32, ''Finding of no significant impact.''

II. Environmental Assessment

Facility Site and Environs

The UMLRR is a heterogeneous open pool non-power reactor that has been in operation since January 1975 for teaching and research purposes. The reactor is licensed to operate at a thermal power of 1.0 MW, and is located on the North Campus of UML, which includes classrooms, offices, and other facilities in an area just north of the Middlesex River.

The UMLRR is housed in a steel-reinforced concrete building. The reactor itself is situated in an open pool, which serves as part of the primary coolant loop as well as moderator, coolant, and shielding. The reactor will be fueled with uranium-silicide and uranium-aluminide low-enriched uranium fuel elements. Waste heat is dissipated via forced-convection cooling at full power, although the reactor can also be cooled via natural convection at lower power levels. A double loop coolant system transfers waste heat from the reactor to the atmosphere via the primary coolant system, heat exchanger, a secondary cooling system, and a cooling tower. Makeup water is provided through municipal water supply (city of Lowell). An Area Radiation Monitoring System continuously monitors gamma and beta radiation levels at locations in the UMLRR facility. A Stack Radiation Monitoring System continuously monitors air exiting the facility through the ventilation system exhaust stack for

airborne radioactivity (gaseous and particulate). Airborne discharges are limited by the UMLRR's technical specifications to ensure that exposure to the general public will not exceed the limits of 10 CFR part 20, ''Standards for Protection against Radiation.''

A detailed description of the reactor can be found in the UMLRR safety analysis report (SAR) submitted by the UML with its renewal application.

Identification of the Proposed Action

The proposed action would renew Facility Operating License No. R–125 for a period of 20 years from the date of issuance of the renewed license. The proposed action is in accordance with UML's application dated October 20, 2015, as supplemented by letters dated March 16, 2016, November 30, 2016, March 31, 2017, July 11, 2017, August 7, 2017, September 13, 2017, January 6, 2018, February 1, 2018, March 5, 2019, April 10, 2019, October 18, 2019, October 24, 2019, December 19, 2019, December 20, 2019, February 24, 2020, September 30, 2020, January 30, 2021, February 16, 2021, April 5, 2021, and April 20, 2021 (collectively referred to as ''the renewal application''). In accordance with 10 CFR 2.109, ''Effect of timely renewal application,'' the existing license remains in effect until the NRC takes final action on the renewal application. As described in the renewal application, UML has also requested NRC review and approval of certain facility changes, and associated changes to the license, in conjunction with the renewal of the license. These include the use of uranium-aluminide fuel elements in addition to the similar uranium-silicide elements currently in use, instrumentation and control upgrades, and re-designation of the reactor containment building as a confinement building.

Need for the Proposed Action

The proposed action is needed to allow the continued operation of the UMLRR, which is used for teaching and research to support the mission of UML, for a period of 20 years from the date of issuance of the renewed license.

Environmental Impacts of the Proposed Action

UML has requested approval of certain facility and license changes in conjunction with license renewal, as previously discussed. However, the proposed action will not require any major physical changes to the facility, or any changes that would significantly affect the operation of the facility, and the operational impacts would be similar to those that have occurred during the current license term. As discussed further, the proposed action will not have a significant environmental impact.

Radiological Impacts

Environmental Effects of Reactor Operations

Gaseous radioactive effluents resulting from the routine operation of the UMLRR are Argon-41 (Ar-41) and Nitrogen-16 (N-16). These nuclides are released to the environment from the reactor building via an exhaust stack on the roof that combines the ventilation exhausts from both the reactor building interior and all attached systems. The UMLRR stack discharge length is 100 feet (30.5 meters) and has an airflow rate of 15,000 cubic feet (7.1 cubic meters) per minute. Because the half-life of N-16 is approximately 7 seconds, the release from the reactor stack is insignificant because most of the N-16 produced in the reactor coolant would decay before reaching the stack. Ar-41 is by far the most significant radionuclide released as a gaseous effluent during normal reactor operations. The maximum release of Ar-41 would occur from continuous operation at full power. UML measured the Ar-41 concentration to be 2.28×10^{-6} microcuries per milliliter exiting the exhaust stack under full power operations. The annual release of Ar-41 under these conditions would be 495 curies (Ci) per year. From this information, UML calculated the maximum annual dose to a member of the public using the ARCON96 computer code to be 14.5 millirem (mrem). This meets the 100 mrem per year (mrem/yr) dose equivalent to the maximally exposed individual in 10 CFR 20.1301, ''Dose limits for individual members of the public.'' UML's annual reports for the 5 years of operation from 2015 through 2019 show that the maximum actual recorded release of Ar-41 was 6.27 Ci in 2015, which the report stated would result in a conservative estimated dose of 0.2 mrem/yr to a member of the public, which is well below the 100 mrem/yr limit specified in 10 CFR 20.1301. This radiation dose of 0.2 mrem/yr also demonstrates compliance with the as low as is reasonably achievable (ALARA) air emissions dose constraint of 10 mrem specified in 10 CFR 20.1101, ''Radiation protection programs,'' paragraph (d).

Liquid radioactive wastes produced as part of the normal operation of the UMLRR are stored in the liquid radioactive waste storage room. From there they are released to the environment via the city of Lowell sanitary sewer system in accordance with 10 CFR 20.2003, ''Disposal by release into sanitary sewerage.'' The water is treated at the Lowell wastewater treatment facility, after which it is discharged to the Merrimack River. The annual reports for the 5 years of operation from 2015 through 2019 show that UML properly disposed of liquid radioactive waste by release into the sanitary sewer system. Based on information presented in the annual reports, radionuclide releases were within the allowable limits specified in 10 CFR part 20, Appendix B, ''Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,'' for liquid effluents.

Low-level solid radioactive waste generated from reactor operations at the UMLRR are primarily demineralizer resins, paper, disposable clothing, gloves, and other miscellaneous contaminated items. These wastes are held to allow for decay and then released for disposal as regular solid wastes if they do not exceed background activity. Otherwise, the wastes are sent to a low-level radioactive waste broker for proper disposal of the wastes containing long-lived radionuclides. The last low-level radioactive waste shipment offsite discussed in the UML annual reports was in May 2017; the shipment consisted of 106 cubic feet (3 cubic meters) of contaminated materials from the reactor as well as other UML campus labs. Once transferred, the low-level waste broker ships and disposes of the waste in accordance with all applicable regulations for radioactive materials. To comply with the Nuclear Waste Policy Act of 1982, UML has entered into a contract with the U.S. Department of Energy (DOE) that provides that DOE retains title to the fuel utilized at UMLRR and that DOE is obligated to take the fuel from the site for final disposition.

As described in Chapter 11 of the UMLRR SAR, and verified through NRC staff review of the UML annual reports for the 5 years of operation from 2015 through 2019, personnel exposures are well within the limits set by 10 CFR 20.1201, ''Occupational dose limits for adults,'' and are ALARA in accordance with 10 CFR 20.1101(b). UML tracks exposures of personnel monitored with dosimeters, and the annual reports for the 5 years of operation from 2015 through 2019 show that the personnel doses were usually less than 10 percent of the occupational limit of 50 milliSieverts (5,000 mrem) per year.

Area thermo-luminescent dosimeter monitors mounted in the control room and the reactor bay provide an additional monthly measurement of total radiation exposures at those locations. No changes in reactor operation that would lead to an increase in occupational dose are expected or proposed as a result of the proposed action.

The radiation monitoring systems associated with reactor operations at UMLRR are provided and maintained as a means of ensuring compliance with radiation limits established under 10 CFR part 20. The UMLRR radiation monitoring systems consist of area monitors, continuous air monitors, portable radiation survey instruments, personnel monitors, and stack particulate and gas monitors. The stack particulate and gas monitoring systems measure the beta-gamma activity emitted by radioactive particulates and the activity of gaseous radioactive nuclides, respectively, that are exhausted through the UMLRR exhaust stack. Perimeter monitoring at UMLRR consists of dosimeters that detect X-ray and gamma radiation.

UML conducts an environmental monitoring program to record and track the radiological impact of UMLRR operation on the surrounding unrestricted area. The environment outside the reactor building is monitored by passive optically stimulated luminescence dosimeters, which are changed out quarterly. These dosimeters are located at strategic locations in and around the Pinanski building, which is attached to the reactor building. The UML Radiation Safety Office analyzes the results to ensure that the reported doses are below 10 CFR part 20 limits, and to monitor for trends that would indicate unusual or elevated exposures. UML states that it has determined that the numbers and placement of environmental dosimeters is sufficient based upon historical data accumulated and analyzed from other dosimetry locations that were part of a previous comprehensive background study of areas around the UML campus. The renewal application provided total annual environmental monitoring dose results from 2009 through 2013 for dosimeters located in the first and third floor airlocks, and 2 locations within the Pinanski building. For each year and location, the measured doses were below 10 mrem and well below the limits to the public as required by 10 CFR part 20. Year-to-year trends in exposures are consistent between monitoring locations. Also, no correlation exists between total annual reactor operation and annual exposures measured at the monitoring locations.

Based on its review of monitoring data in the renewal application, the NRC staff concludes that operation of the UMLRR does not have any significant radiological impact on the surrounding environment. No changes in reactor operation that would affect normal off-site radiation levels are expected or proposed as a result of the proposed action. Therefore, the proposed action would not have a significant radiological impact.

Environmental Effects of Accidents

Accident scenarios are discussed in Chapter 13 of the UMLRR SAR. The accidents analyzed in Chapter 13 range from anticipated events to a postulated fission product release with radiological consequences that exceed those of any accident considered to be credible. This limiting accident is referred to as the maximum hypothetical accident (MHA). UML considers the uncontrolled release of the volatile gaseous fission products to be the MHA for UMLRR. This accident would involve the removal of the cladding from one side of one fuel plate while the fuel is in the reactor pool. From there, the release would continue to the reactor confinement building and into the environment. UML uses this scenario to calculate the maximum concentration of fission products that might be present in the reactor room air following the MHA. From its calculations, UML concluded that individual worker exposures from the MHA would not exceed 10 CFR part 20 dose limits and that all effluent releases to the environment resulting from the MHA would also meet 10 CFR part 20 dose limits.

Separate from this EA, the NRC staff is reviewing UML's MHA analyses of the potential radiological consequences that may result from the proposed license renewal. The results of the NRC staff's safety review will be documented in a safety evaluation report that will be made publicly available. If the NRC concludes that the radiological consequences of the MHA are within 10 CFR part 20 dose limits, then the MHA and the proposed action would not have a significant impact with respect to the radiological consequences of the MHA.

Conclusions

Because, in the renewal application, UML has not proposed any physical changes to the reactor facility design, or changes to facility operating conditions, that would significantly affect facility operation, there would be no changes in the types or quantities of routine effluents that may be released off site. UML has systems in place for controlling the release of radiological effluents and implements a radiation protection program to monitor personnel exposures and releases of radioactive effluents. Accordingly, there would be no increase in routine occupational or public radiation exposure as a result of the proposed action. As previously discussed, a separate safety evaluation is being conducted by the NRC staff to determine the probability and consequences of accidents that could result from the proposed action. If the safety evaluation finds that the probability and consequences of accidents are within NRC regulatory requirements, then the proposed action would have no significant environmental impact with respect to accidents.

License renewal would not significantly change reactor operations. As previously discussed, information in the renewal application and data reported to the NRC by UML for the last 5 years of reactor operations were evaluated to determine the radiological impact of reactor operations. The NRC staff found that releases of radioactive material and personnel exposures were all well within applicable regulatory limits. Based on this evaluation, the proposed action would have no significant radiological impacts.

Non-Radiological Impacts

The proposed action does not involve any significant change in the operation of the reactor, change in the emissions or heat load dissipated to the environment, or involve construction or other land disturbance activities. The proposed action would not result in any land use changes or increases in noise or air emissions and would not have a significant impact on air quality, noise, or visual resources. Water is supplied through the city water utility and UML proposes no increase in water use or effluent discharge. Thus, the proposed action would not incrementally affect surface water or groundwater resources. There is no potential for the proposed action to affect aquatic or terrestrial resources, or any other environmental resource conditions. Therefore, the proposed action would have no significant non-radiological impacts.

Other Applicable Environmental Laws

In addition to the National Environmental Policy Act, which requires Federal agencies to consider the environmental impacts of proposed actions, the NRC has responsibilities that are derived from other environmental laws and policy directives, which include the

Endangered Species Act (ESA), Coastal Zone Management Act (CZMA), Fish and Wildlife Coordination Act (FWCA), National Historic Preservation Act (NHPA), and Executive Order 12898, ''Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629). The following presents a summary of impacts associated with resources protected by these laws and related requirements.

Endangered Species Act

The ESA was enacted to prevent further decline of endangered and threatened species and restore those species and their critical habitat. Section 7 of the ESA requires Federal agencies to consult with the U.S. Fish and Wildlife Service (FWS) or National Marine Fisheries Service (NMFS) regarding actions that may affect listed species or designated critical habitats.

The NRC staff conducted a search of federally listed species and critical habitats that have the potential to occur in the vicinity of the UMLRR using the FWS's Environmental Conservation Online System. Three federally listed species occur in Middlesex County, Massachusetts: The red knot (*Calidris canutus rufa*), small whorled pogonia (*Isotria medeoloides*), and northern long-eared bat (*Myotis septentrionalis*). However, none of these species are likely to occur near the UMLRR because it is located on the UML campus. The campus does not provide suitable habitat for federally listed species because it has been developed and in use for research and educational purposes for many decades. Additionally, operation of the UMLRR has no direct nexus to the natural environment that would otherwise affect federally listed species. Accordingly, the proposed action would have no effect on federally listed species or critical habitats. Federal agencies are not required to consult with the FWS if they determine that an action will not affect listed species or critical habitats. Thus, the ESA does not require consultation for the proposed UMLRR license renewal, and the NRC considers its obligations under ESA Section 7 to be fulfilled for the proposed action.

Coastal Zone Management Act

The CZMA, in part, encourages States to preserve, protect, develop, and restore coastal resources. Applicants for Federal licenses to conduct an activity that affects any land or water use or natural resource of the coastal zone of a State must provide a certification stating that the proposed activity complies with the State's approved coastal zone management program and that the applicant will conduct activities consistent with that program.

Middlesex County, Massachusetts, does not contain any coastal zones. Because the UMLRR is not located within or near any managed coastal zones, the proposed action would not affect any coastal zones and CZMA consistency certification does not apply. Therefore, UML does not need to provide a certification under the CZMA.

Fish and Wildlife Coordination Act

The FWCA requires Federal agencies that license water resource development projects to consult with the FWS (or NMFS, when applicable) and the State wildlife resource agencies regarding the potential impacts of the project on fish and wildlife resources.

The proposed action does not involve any water resource development projects, including any modifications relating to impounding a body of water, damming, diverting a stream or river, deepening a channel, irrigation, or altering a body of water for navigation or drainage. Therefore, no coordination with other agencies pursuant to the FWCA is required for the proposed action.

National Historic Preservation Act

The NHPA requires Federal agencies to consider the effects of their undertakings on historic properties. As stated in the Act, historic properties are any prehistoric or historic district, site, building, structure, or object included in, or eligible for inclusion in the National Register of Historic Places (NRHP). The NRHP lists several historic properties in Middlesex County within 0.6 miles (1 kilometer) of the UMLRR. Operation of the UMLRR has not likely had any impact on any of these properties. The nearest historic property, which is located about 0.3 miles (0.5 kilometers) from the UMLRR, is the St. Joseph's Convent and School (National Register Listing No. 02000789). The location of this historic property is completely surrounded by development, and the view towards the UMLRR is obstructed by commercial and industrial properties. Based on this information, the proposed action would have no adverse effect on historic properties in the vicinity of the UMLRR. By letter dated November 26, 2018, the NRC staff contacted the Massachusetts State Historic Preservation Officer (SHPO) and discussed the proposed action. On January 2, 2019, the SHPO indicated concurrence with the NRC staff's determination that the proposed action would have no adverse effect on historic properties.

Executive Order 12898—Environmental Justice

Executive Order 12898 directs Federal agencies to identify and address the disproportionately high and adverse human health or environmental effects of their actions on minority and low-income populations to the greatest extent practicable and permitted by law.

The environmental justice impact analysis evaluates the potential for disproportionately high and adverse human health or environmental effects on minority and low-income populations that could result from the proposed action. Such effects may include human health, biological, cultural, economic, or social impacts. Minority and low-income populations are subsets of the general public residing around the UMLRR, and all are exposed to the same health and environmental effects generated from activities at the UMLRR.

Minority Populations in the Vicinity of the UMLRR—According to the U.S. Census Bureau's 2010 Census, approximately 31 percent of the total population (approximately 505,000 individuals) residing within a 10-mile (16-kilometer) radius of the UMLRR identified themselves as minorities. The largest minority populations were Hispanic, Latino, or Spanish origin of any race (approximately 90,000 or 18 percent) followed by Asian (approximately 43,000 or 8.5 percent). According to the 2010 Census, 23.5 percent of the Middlesex County population identified themselves as minorities, with persons of Asian and Hispanic, Latino, or Spanish origin of any race comprising the largest minority populations (9.3 percent and 6.5 percent, respectively). According to the U.S. Census Bureau's 2019 American Community Survey 1-year Estimates, the minority population of Middlesex County, as a percent of the total population, had increased to about 30 percent.

Low-Income Populations in the Vicinity of the UMLRR—According to the U.S. Census Bureau's 2015–2019 American Community Survey 5-Year Estimates, approximately 54,000 persons and 10,000 families (approximately 10 and 7 percent, respectively) residing within a 10-mile (16-kilometer) radius of the UMLRR were identified as living below the Federal poverty threshold. The 2019 Federal poverty threshold was $26,172 for a family of four.

According to the U.S. Census Bureau's 2019 American Community

Survey Census 1-Year Estimates, the median household income for Massachusetts was $85,843 while approximately 6 percent of families and 9 percent of the State population were found to be living below the Federal poverty threshold. Middlesex County had a higher median household income average ($107,056) and a lower percentage of families (4 percent) and persons (7 percent) living below the poverty level.

Impact Analysis—Potential impacts to minority and low-income populations would mostly consist of radiological effects; however, radiation doses from continued operations associated with the license renewal are expected to continue at current levels and would be well below regulatory limits.

Based on this information and the analysis of human health and environmental impacts presented in this EA, the proposed license renewal action would not have disproportionately high and adverse human health or environmental effects on minority and low-income populations residing near the UMLRR.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to license renewal, the NRC considered denying the proposed action (*i.e.,* the ''no-action'' alternative). If the NRC denied the renewal application, reactor operations would cease, and decommissioning would be required sooner than if a renewed license were issued. The NRC notes that, even with a renewed license, UMLRR will eventually be decommissioned, at which time the environmental effects of decommissioning would occur. Decommissioning would be conducted in accordance with an NRC-approved decommissioning plan, which would require a separate environmental review under 10 CFR 51.21. Cessation of reactor operations would reduce or eliminate radioactive effluents. However, as previously discussed in this EA, radioactive effluents from reactor operations constitute a small fraction of the applicable regulatory limits. Therefore, the environmental impacts of license renewal and the denial of the renewal application would be similar. In addition, denying the renewal application would eliminate the benefits of teaching, research, and services provided by the UMLRR.

Alternative Use of Resources

There are no unresolved conflicts concerning alternative uses of available resources under the proposed action. Further, the proposed action does not involve the use of any different resources or significant quantities of resources beyond those previously considered in the renewal of Facility Operating License No. R–125 for the UMLRR in November 1985, which previously renewed the UMLRR license for a period of 30 years.

Agencies and Persons Consulted

As discussed previously, the NRC staff consulted with the Massachusetts SHPO regarding the proposed action. Additionally, in accordance with NRC policy, the NRC staff consulted with the Commonwealth of Massachusetts Liaison Officer on March 17 and March 26, 2021, regarding the environmental impact of the proposed action, and explained the environmental reviews and forwarded a draft of this EA. On April 20, 2021, the Commonwealth of Massachusetts official indicated, by electronic mail, that they had no comments regarding the proposed action.

III. Finding of No Significant Impact

The NRC is considering renewal of Facility Operating License No. R–125, held by UML, which would authorize the continued operation of the UMLRR for an additional 20 years from the date of issuance of the renewed license.

On the basis of the EA included in Section II of this notice and incorporated by reference in this finding, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment, and will not significantly affect the environment surrounding the UMLRR. This is because the proposed action will result in no significant radiological impacts from continued operations as the types or quantities of effluents that may be released off site would not change. No changes in land use would occur or increases in noise or air emissions. Continued operations under the proposed action would have no significant impacts on air quality, noise, visual resources, surface water or groundwater resources, terrestrial or aquatic resources, or on any other environmental resource conditions. Additionally, the proposed action would have no effect on federally listed species or designated critical habitats, would not affect historic properties, and would not result in environmental justice impacts. Therefore, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

The NRC considered information provided in UML's application, as supplemented, and the review of related environmental documents. Section IV of this notice lists the documents related to the proposed action and includes information on the availability of these documents.

IV. Availability of Documents

The following table identifies the references cited in this document and related to the NRC's FONSI. Documents with an ADAMS accession number are available for public inspection online through ADAMS at *https://www.nrc.gov/reading-rm/adams.html.*

Document	ADAMS Accession No.
University of Massachusetts Lowell, Request for Renewal of Facility Operating License R–125 and SAR, dated October 20, 2015.	ML16042A015 (Package).
University of Massachusetts Lowell, Submittal of Revision 2 to Operator Requalification Program, dated March 16, 2016	ML16076A405 (Package).
University of Massachusetts Lowell, Response to NRC Request for Additional Information Regarding the Operator Requalification Program for License Renewal and Submittal of Revision 3 to Operator Requalification Program, dated November 30, 2016.	ML16335A327 (Package).
University of Massachusetts Lowell, Response to NRC Request for Additional Information for License Renewal, dated March 31, 2017.	ML17090A348 (Package).
University of Massachusetts Lowell, Response to NRC Request for Additional Information Regarding Financial Qualifications for License Renewal, dated July 11, 2017.	ML17192A428 (Package).
University of Massachusetts Lowell, Response to NRC Request for Additional Information Regarding the Physical Security Plan for License Renewal and Submittal of Revision 8 to Physical Security Plan, dated August 7, 2017.	ML17222A071.
University of Massachusetts Lowell, Submittal of Revision 9 to Physical Security Plan, dated September 13, 2017	ML17261A211.

Document	ADAMS Accession No.
University of Massachusetts Lowell, Response to NRC Request for Additional Information for License Renewal, dated January 6, 2018.	ML18006A003 (Package).
University of Massachusetts Lowell, Additional Clarifying Information for License Renewal, dated February 1, 2018	ML18032A534 (Package).
University of Massachusetts Lowell, Response to NRC Request for Additional Information Primarily Related to Technical Specifications, dated March 5, 2019.	ML19064B373 (Package).
University of Massachusetts Lowell, Submittal of Revised SAR Section 7.4.1.2, dated April 10, 2019	ML19100A273.
University of Massachusetts Lowell, Response to NRC Request for Additional Information Primary Related to Instrumentation and Controls, dated October 18, 2019.	ML19291C293.
University of Massachusetts Lowell, Supplement to October 18, 2019, Response to NRC Request for Additional Information, dated October 24, 2019.	ML19297F433.
University of Massachusetts Lowell, Second Supplement to October 18, 2019, Response to NRC Request for Additional Information, dated December 19, 2019.	ML19353C523.
University of Massachusetts Lowell, Supplement to December 19, 2019, Letter, dated December 20, 2019	ML19354A610.
University of Massachusetts Lowell, Response to Items 7.4.c and 7.5.a from NRC Request for Additional Information Primarily Related to Instrumentation and Controls, dated February 24, 2020.	ML20055F604.
University of Massachusetts Lowell, Supplemental Information Provided in Response to Audit, dated September 30, 2020	ML20274A248 (Package).
University of Massachusetts Lowell, Supplemental Information Provided in Response to Audit, dated January 30, 2021	ML21030A004 (Package).
University of Massachusetts Lowell, Supplemental Information Provided in Response to Audit, dated February 16, 2021	ML21047A245.
University of Massachusetts Lowell, Request for Additional Language in Proposed License Conditions, dated April 5, 2021	ML21095A245.
University of Massachusetts Lowell, Review of Renewal License Conditions, dated April 20, 2021	ML21110A053.
University of Massachusetts Lowell, 2015–2016 Annual Operating Report, dated August 11, 2016	ML16224A326.
University of Massachusetts Lowell, 2016–2017 Annual Operating Report, dated July 28, 2017	ML17209A491.
University of Massachusetts Lowell, 2017–2018 Annual Operating Report, dated August 15, 2018	ML18227A980 (Package).
University of Massachusetts Lowell, 2018–2019 Annual Operating Report, dated August 30, 2019	ML19248C113 (Package).
University of Massachusetts Lowell, 2019–2020 Annual Operating Report, dated August 25, 2020	ML20238C002.
U.S. Fish and Wildlife Service, Endangered Species Consultations Frequently Asked Questions, dated July 15, 2013	ML16120A505.
U.S. Nuclear Regulatory Commission, Letter to Massachusetts State Historic Preservation Officer, dated November 26, 2018	ML18320A135 (Package).
Massachusetts Historical Commission, Massachusetts State Historical Preservation Officer Concurrence, dated January 2, 2019.	ML19011A400.
Massachusetts Emergency Management Agency, Electronic Mail Indicating No Comments, dated April 20, 2021	ML21111A358.

Dated: July 30, 2021.

For the Nuclear Regulatory Commission.

Joshua M. Borromeo,

Chief, Non-Power Production and Utilization Facility Licensing Branch, Division of Advanced Reactors and Non-Power, Production and Utilization Facilities, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–16590 Filed 8–3–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0039]

Information Collection: Standards for Protection Against Radiation

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a proposed collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Standards for Protection Against Radiation.''

DATES: Submit comments by September 3, 2021. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0039 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 *https://www.regulations.gov/* and search for Docket ID NRC–2021–0039.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://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.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession Nos. ML21207A110 and ML21207A112. The

supporting statement and is ADAMS under Accession No. ML21154A178.

• *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *https://www.regulations.gov/* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

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

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a proposed collection of information to OMB for review entitled ''Standards for Protection Against Radiation.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on March 22, 2021 (86 FR 15273).

1. *The title of the information collection:* Part 20 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Standards for Protection Against Radiation.''

2. *OMB approval number:* An OMB control number has not yet been assigned to this proposed information collection.

3. *Type of submission:* New.

4. *The form number, if applicable:* Not applicable.

5. *How often the collection is required or requested:* Annually for most reports and at license termination for reports dealing with decommissioning.

6. *Who will be required or asked to respond:* NRC licensees and Agreement State licensees, including those requesting license terminations. Types of licensees include civilian commercial, industrial, academic, and medical users of nuclear materials. Licenses are issued for, among other things, the possession, use, processing, handling, and importing and exporting of nuclear materials, and for the operation of nuclear reactors.

7. *The estimated number of annual responses:* 52,359.

8. *The estimated number of annual respondents:* 25,225.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 769,396.

10. *Abstract:* 10 CFR part 20 establishes standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the NRC and by Agreement States. These standards require the establishment of radiation protection programs, maintenance of radiation protection programs, maintenance of radiation records, recording of radiation received by workers, reporting of incidents which could cause exposure to radiation, submittal of an annual report to NRC and to Agreement States of the results of individual monitoring, and submittal of license termination information. These mandatory requirements are needed to protect occupationally exposed individuals from undue risks of excessive exposure to ionizing radiation and to protect the health and safety of the public.

Dated: July 29, 2021.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2021–16546 Filed 8–3–21; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–117 and CP2021–119; MC2021–118 and CP2021–120]

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 negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 6, 2021.

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:

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I. Introduction
II. Docketed Proceeding(s)

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 3011.301.[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 3030, and 39 CFR part 3040, 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 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2021–117 and CP2021–119; *Filing Title:* USPS Request to Add Priority Mail Contract 715 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 29, 2021; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 6, 2021.

2. *Docket No(s).:* MC2021–118 and CP2021–120; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & First-Class Package Service Contract 75 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 29, 2021; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 6, 2021.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2021–16593 Filed 8–3–21; 8:45 am]

BILLING CODE 7710–FW–P

[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).

POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 86 FR 40882.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Thursday, August 5, 2021, at 10:00 a.m.; and Friday, August 6, 2021, at 9:00 a.m.

CHANGES IN THE MEETING: The Postal Service will not hold a public comment period following the open session of this meeting. The Postal Service has decided to continue the suspension of public in-person attendance for the open session of this meeting due to the pandemic. Individuals may listen to the open session of the meeting through a livestream. Details for listening to the livestream are available on the Postal Service's website, *https://about.usps.com/who/leadership/board-governors.*

CONTACT PERSON FOR MORE INFORMATION: Michael J. Elston, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–1000. Telephone: (202) 268–4800.

Michael J. Elston,

Secretary.

[FR Doc. 2021–16749 Filed 8–2–21; 4:15 pm]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92524; File No. SR–FINRA–2021–014]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change Relating to Members' Filing Requirements Under FINRA Rule 6432 (Compliance With the Information Requirements of SEA Rule 15c2–11)

July 29, 2021.

On May 28, 2021, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''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 amend members' filing requirements under FINRA Rule 6432 (Compliance with the Information Requirements of Securities Exchange Act Rule 15c2–11). The proposed rule change was published for comment in the **Federal Register** on June 15, 2021.[3]

Section 19(b)(2) of the Act[4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is July 30, 2021. The Commission is extending this 45-day period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change and the comment received. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates September 13, 2021 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–FINRA–2021–014).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–16550 Filed 8–3–21; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] See Exchange Act Release No. 92139 (June 9, 2021), 86 FR 31774 (June 15, 2021). Comments on the proposed rule change can be found at: *https://www.sec.gov/comments/sr-finra-2021-014/srfinra2021014.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

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 October 4, 2021.

ADDRESSES: Send all comments to, Cynthia Pitts, Director, Disaster Administrative Services, Office of Disaster Assistance, *cynthia.pitts@sba.gov* Small Business Administration.

FOR FURTHER INFORMATION CONTACT: Cynthia Pitts, Director, Disaster Administrative Services, Office of Disaster Assistance, Small Business Administration, *Cynthia.pitts@sba.gov,* Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov;* Application for benefits (loan) used to determine eligibility and credit worthiness of small businesses or not for profit organization who seek Federal assistance in a declared disaster. Respondents are disaster survivors seeking disaster assistance.

SUPPLEMENTARY INFORMATION: Application for benefits (grant) used to determine eligibility and credit worthiness of applicants who seek Federal grant assistance. Respondents are live venue operator or promotor, theatrical producer, or live performing arts organization operator, museum operator, motion picture theatre operator, or talent representative.

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

OMB Control No: 3245–0420.

(1) *Title:* Shuttered Venues Grant Application.

Description of Respondents: Eligible persons or entities seeking grant assistance: A live venue operator or promoter, theatrical producer, or live performing arts organization operator, museum operator, motion picture theatre operator, or talent representative.

Form Number: SBA Form 3515.

Total Estimated Annual Responses: 30,000.

Total Estimated Annual Hour Burden: 60,000.

Curtis Rich,

Management Analyst.

[FR Doc. 2021–16533 Filed 8–3–21; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17054 and #17055; Pennsylvania Disaster Number PA–00111]

Administrative Declaration of a Disaster for the Commonwealth of Pennsylvania

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the Commonwealth of Pennsylvania dated 07/29/2021. Incident: Flash Flooding. Incident Period: 07/12/2021.

DATES: Issued on 07/29/2021.

Physical Loan Application Deadline Date: 09/27/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 04/29/2022.

ADDRESSES: *Submit completed loan applications to:* U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Bucks, Philadelphia, Tioga.

Contiguous Counties:

Pennsylvania: Bradford, Delaware, Lehigh, Lycoming, Montgomery, Northampton, Potter.

New Jersey: Burlington, Camden, Gloucester, Hunterdon, Mercer, Warren.

New York: Chemung, Steuben.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	3.250
Homeowners without Credit Available Elsewhere	1.625
Businesses with Credit Available Elsewhere	5.760
Businesses without Credit Available Elsewhere	2.880
Non-Profit Organizations with Credit Available Elsewhere	2.000
Non-Profit Organizations without Credit Available Elsewhere	2.000
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	2.880
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 17054 6 and for economic injury is 17055 0. The States which received an EIDL Declaration # are New Jersey, New York, Pennsylvania.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2021–16532 Filed 8–3–21; 8:45 am]

BILLING CODE 8026–03–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Conforming Amendment to Product Exclusion: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: Effective July 1, 2021, the U.S. International Trade Commission (USITC) implemented certain changes to statistical reporting categories in the Harmonized Tariff Schedule of the United States (HTSUS). To conform with these changes, this notice makes a technical amendment to a product exclusion in this Section 301 investigation.

DATES: The conforming amendment in the Annex to this notice is applicable as of July 1, 2021.

FOR FURTHER INFORMATION CONTACT: For general questions about this notice, contact Associate General Counsel Philip Butler at (202) 395–5725. For specific questions on customs classification or implementation of the product exclusion identified in the Annex to this notice, contact *traderemedy@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

On July 1, 2021, the USITC, in cooperation with the interagency Committee for Statistical Annotation of Tariff Schedules, implemented certain changes in ten-digit statistical reporting categories of the HTSUS and in

Schedule B under section 484(f) of the Tariff Act of 1930, 19 U.S.C. 1484(f). One of the product exclusions in the Section 301 investigation of China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, as set out at 85 FR 85831 (December 29, 2020) and 86 FR 13785 (March 10, 2021), is based on one of the amended statistical reporting categories.

B. Technical Amendment to Exclusion

The Annex to this notice conforms an existing product exclusion with the July 1, 2021 changes to ten-digit statistical reporting categories in the HTSUS. In particular, the Annex makes a technical amendment to U.S. note 20(qqq)(4) to subchapter III of chapter 99 of the HTSUS, as set out in the Annexes to the notices published at 85 FR 85831 (December 29, 2020) and 86 FR 13785 (March 10, 2021).

Annex

Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on July 1, 2021, U.S. note 20(qqq)(4) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is modified by deleting ''3808.94.5090'' and inserting ''3808.94.5090 prior to July 1, 2021; 3808.94.5080 or 3808.94.5095 effective July 1, 2021'' in lieu thereof.

Greta Peisch,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2021–16567 Filed 8–3–21; 8:45 am]

BILLING CODE 3290–F1–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0009]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of denials.

SUMMARY: FMCSA announces its decision to deny applications from 27 individuals who requested an exemption from the vision standard in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a CMV in interstate commerce.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing materials in the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–2021–0009, in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

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 *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

FMCSA received applications from 27 individuals who requested an exemption from the vision standard in the FMCSRs.

FMCSA has evaluated the eligibility of these applicants and concluded that granting these exemptions would not provide a level of safety that would be equivalent to, or greater than, the level of safety that would be obtained by complying with § 391.41(b)(10).

III. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. FMCSA grants exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on medical reports about the applicants' vision, as well as their driving records and experience driving with the vision deficiency.

IV. Conclusion

The Agency has determined that these applicants do not satisfy the eligibility criteria or meet the terms and conditions of the Federal exemption and granting these exemptions would not provide a level of safety that would be equivalent to, or greater than, the level of safety that would be obtained by complying with § 391.41(b)(10). Therefore, the 27 applicants in this notice have been denied exemptions from the physical qualification standards in § 391.41(b)(10).

Each applicant has, prior to this notice, received a letter of final disposition regarding his/her exemption request. Those decision letters fully outlined the basis for the denial and constitute final action by the Agency. This notice summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4) by periodically publishing names and reasons for denial.

The following applicant, Michael S. Hundley (KS), did not have sufficient driving experience over the past three years under normal highway operating conditions:

The following 11 applicants had no experience operating a CMV:

Erik R. Almquist (NC)
Gregory M. Flowers (MS)
Alexander A.D. Garcia (CA)
Kenrick W. Hamilton (NV)
Cody R. Hare (PA)
Thomas W. Kurutz (PA)
William F. McEvoy (IL)
Kyle R. Mckenna (WA)
Joel R. Mitchell (FL)
Abdi S. Negeri (OR)
Merhawi Tesfay (NV)

The following five applicants did not have 3 years of experience driving a CMV on public highways with their vision deficiencies:

Bryan J. Teaster (NC)
Robbie R. Austin (ID)
Owen R. Powell (WI)
Jared L. Coleman (VA)
Zachary J. Rowzee (MS)

The following two applicants did not have 3 years of recent experience driving a CMV on public highways with their vision deficiencies:

Russell Askew (KS); Terrance A. Nicely (IN)

The following three applicants did not have sufficient driving experience over the past 3 years under normal

highway operating conditions (gaps in driving record):

Mario A. Martinez Borroto (TX); James E. Marsh (UT); Donald L. Elsberry (IA)

The following applicant, Charles D. Parks (OH), did not demonstrate the level of safety required for interstate driving (excessive moving/non-moving violations during 3-year period).

The following two applicants were denied for multiple reasons:

Jason Beer (NE); Armando Palomino Gonzalez (OK)

The following applicant, Dave Counts (IN), has not had stable vision for the preceding 3-year period.

The following applicant, Jatinder K. Mahi (CA), does not meet the vision standard in his better eye.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–16541 Filed 8–3–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0007]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 13 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. They are unable to meet the vision requirement in one eye for various reasons. The exemptions enable these individuals to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: The exemptions were applicable on July 10, 2021. The exemptions expire on July 10, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–2021–0007, in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

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 *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

On June 9, 2021, FMCSA published a notice announcing receipt of applications from 13 individuals requesting an exemption from vision requirement in 49 CFR 391.41(b)(10) and requested comments from the public (86 FR 30672). The public comment period ended on July 9, 2021, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in § 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on medical reports about the applicants' vision, as well as their driving records and experience driving with the vision deficiency. The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the June 9, 2021, **Federal Register** notice (86 FR 30672) and will not be repeated here.

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their limitation and demonstrated their ability to drive safely. The 13 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, cataracts, corneal scarring, macular scarring, prosthesis, retinal deformity, retinal detachment, and retinal scarring. In most cases, their eye conditions did not develop recently. Nine of the applicants were either born with their vision impairments or have had them since childhood. The four individuals that developed their vision conditions as adults have had them for a range of 4 to 30 years. Although each applicant has one eye that does not meet the vision requirement in § 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and, in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV.

Doctors' opinions are supported by the applicants' possession of a valid license to operate a CMV. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV with their limited vision in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. We believe that the applicants' intrastate

driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions.

The applicants in this notice have driven CMVs with their limited vision in careers ranging for 5 to 80 years. In the past 3 years, no drivers were involved in crashes, and 2 drivers were convicted of moving violations in CMVs. All the applicants achieved a record of safety while driving with their vision impairment that demonstrates the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

Consequently, FMCSA finds that in each case exempting these applicants from the vision requirement in § 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and includes the following: (1) Each driver must be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in § 391.41(b)(10) and (b) by a certified medical examiner (ME) who attests that the individual is otherwise physically qualified under § 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the ME at the time of the annual medical examination; and (3) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 13 exemption applications, FMCSA exempts the following drivers from the vision requirement, § 391.41(b)(10), subject to the requirements cited above:

Gerald C. Adler (NH)

Paul R. Beckett (MN)

Robert W. Boyett (GA)

Timothy W. Ford (SC)

Aaron L. Fox (OH)

James H. George (PA)

Johnny M. Kruprzak (OH)

Jackie L. Lawson (VA)

Alec J Lindgren (NY)

James M. McCleary (OH)

Richard A. Parker II (KS)

Robert B. Sundvor (ND)

William R. Tessman (TX)

In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–16542 Filed 8–3–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1998–4334; FMCSA–1999–5578; FMCSA–2000–7363; FMCSA–2001–9258; FMCSA–2001–9561; FMCSA–2002–11714; FMCSA–2002–13411; FMCSA–2003–14223; FMCSA–2003–14504; FMCSA–2003–15268; FMCSA–2005–20560; FMCSA–2005–21254; FMCSA–2006–25246; FMCSA–2006–26066; FMCSA–2006–26653; FMCSA–2007–2663; FMCSA–2007–27333; FMCSA–2007–27515; FMCSA–2007–27897; FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2008–0340; FMCSA–2008–0398; FMCSA–2009–0054; FMCSA–2009–0086; FMCSA–2009–0121; FMCSA–2009–0154; FMCSA–2009–0291; FMCSA–2010–0082; FMCSA–2010–0187; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2010–0413; FMCSA–2011–0010; FMCSA–2011–0024; FMCSA–2011–0092; FMCSA–2011–0102; FMCSA–2011–0140; FMCSA–2012–0040; FMCSA–2012–0215; FMCSA–2012–0279; FMCSA–2012–0337; FMCSA–2013–0022; FMCSA–2013–0024; FMCSA–2013–0025; FMCSA–2013–0027; FMCSA–2013–0028; FMCSA–2013–0029; FMCSA–2013–0030; FMCSA–2014–0007; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2014–0298; FMCSA–2014–0302; FMCSA–2014–0304; FMCSA–2014–0305; FMCSA–2015–0048; FMCSA–2015–0049; FMCSA–2015–0052; FMCSA–2015–0053; FMCSA–2015–0055; FMCSA–2015–0072; FMCSA–2016–0030; FMCSA–2016–0033; FMCSA–2016–0206; FMCSA–2016–0208; FMCSA–2016–0212; FMCSA–2016–0213; FMCSA–2016–0214; FMCSA–2017–0014; FMCSA–2017–0017; FMCSA–2017–0019; FMCSA–2017–0020; FMCSA–2018–0017; FMCSA–2019–0005; FMCSA–2019–0009; FMCSA–2019–0011]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 123 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirements in one eye.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before September 3, 2021.

ADDRESSES: You may submit comments identified by the Federal Docket

Management System (FDMS) Docket No. FMCSA–1998–4334, Docket No. FMCSA–1999–5578, Docket No. FMCSA–2000–7363, Docket No. FMCSA–2001–9258, Docket No. FMCSA–2001–9561, Docket No. FMCSA–2002–11714, Docket No. FMCSA–2002–13411, Docket No. FMCSA–2003–14223, Docket No. FMCSA–2003–14504, Docket No. FMCSA–2003–15268, Docket No. FMCSA–2005–20560, Docket No. FMCSA–2005–21254, Docket No. FMCSA–2006–25246, Docket No. FMCSA–2006–26066, Docket No. FMCSA–2006–26653, Docket No. FMCSA–2007–2663, Docket No. FMCSA–2007–27333, Docket No. FMCSA–2007–27515, Docket No. FMCSA–2007–27897, Docket No. FMCSA–2008–0021, Docket No. FMCSA–2008–0106, Docket No. FMCSA–2008–0340, Docket No. FMCSA–2008–0398, Docket No. FMCSA–2009–0054, Docket No. FMCSA–2009–0086, Docket No. FMCSA–2009–0121, Docket No. FMCSA–2009–0154, Docket No. FMCSA–2009–0291, Docket No. FMCSA–2010–0082, Docket No. FMCSA–2010–0187, Docket No. FMCSA–2010–0354, Docket No. FMCSA–2010–0385, Docket No. FMCSA–2010–0413, Docket No. FMCSA–2011–0010, Docket No. FMCSA–2011–0024, Docket No. FMCSA–2011–0092, Docket No. FMCSA–2011–0102, Docket No. FMCSA–2011–0140, Docket No. FMCSA–2012–0040, Docket No. FMCSA–2012–0215, Docket No. FMCSA–2012–0279, Docket No. FMCSA–2012–0337, Docket No. FMCSA–2013–0022, Docket No. FMCSA–2013–0024, Docket No. FMCSA–2013–0025, Docket No. FMCSA–2013–0027, Docket No. FMCSA–2013–0028, Docket No. FMCSA–2013–0029, Docket No. FMCSA–2013–0030, Docket No. FMCSA–2014–0007, Docket No. FMCSA–2014–0011, Docket No. FMCSA–2014–0296, Docket No. FMCSA–2014–0298, Docket No. FMCSA–2014–0302, Docket No. FMCSA–2014–0304, Docket No. FMCSA–2014–0305, Docket No. FMCSA–2015–0048, Docket No. FMCSA–2015–0049, Docket No. FMCSA–2015–0052, Docket No. FMCSA–2015–0053, Docket No. FMCSA–2015–0055, Docket No. FMCSA–2015–0072, Docket No. FMCSA–2016–0030, Docket No. FMCSA–2016–0033, Docket No. FMCSA–2016–0206, Docket No. FMCSA–2016–0208, Docket No. FMCSA–2016–0212, Docket No. FMCSA–2016–0213, Docket No. FMCSA–2016–0214, Docket No. FMCSA–2017–0014, Docket No. FMCSA–2017–0017, Docket No. FMCSA–2017–0019, Docket No. FMCSA–2017–0020, Docket No. FMCSA–2018–0017, Docket No. FMCSA–2019–0005, Docket No. FMCSA–2019–0009, or Docket No. FMCSA–2019–0011 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/,* insert the docket number, FMCSA–1998–4334, FMCSA–1999–5578, FMCSA–2000–7363, FMCSA–2001–9258, FMCSA–2001–9561, FMCSA–2002–11714, FMCSA–2002–13411, FMCSA–2003–14223, FMCSA–2003–14504, FMCSA–2003–15268, FMCSA–2005–20560, FMCSA–2005–21254, FMCSA–2006–25246, FMCSA–2006–26066, FMCSA–2006–26653, FMCSA–2007–2663, FMCSA–2007–27333, FMCSA–2007–27515, FMCSA–2007–27897, FMCSA–2008–0021, FMCSA–2008–0106, FMCSA–2008–0340, FMCSA–2008–0398, FMCSA–2009–0054, FMCSA–2009–0086, FMCSA–2009–0121, FMCSA–2009–0154, FMCSA–2009–0291, FMCSA–2010–0082, FMCSA–2010–0187, FMCSA–2010–0354, FMCSA–2010–0385, FMCSA–2010–0413, FMCSA–2011–0010, FMCSA–2011–0024, FMCSA–2011–0092, FMCSA–2011–0102, FMCSA–2011–0140, FMCSA–2012–0040, FMCSA–2012–0215, FMCSA–2012–0279, FMCSA–2012–0337, FMCSA–2013–0022, FMCSA–2013–0024, FMCSA–2013–0025, FMCSA–2013–0027, FMCSA–2013–0028, FMCSA–2013–0029, FMCSA–2013–0030, FMCSA–2014–0007, FMCSA–2014–0011, FMCSA–2014–0296, FMCSA–2014–0298, FMCSA–2014–0302, FMCSA–2014–0304, FMCSA–2014–0305, FMCSA–2015–0048, FMCSA–2015–0049, FMCSA–2015–0052, FMCSA–2015–0053, FMCSA–2015–0055, FMCSA–2015–0072, FMCSA–2016–0030, FMCSA–2016–0033, FMCSA–2016–0206, FMCSA–2016–0208, FMCSA–2016–0212, FMCSA–2016–0213, FMCSA–2016–0214, FMCSA–2017–0014, FMCSA–2017–0017, FMCSA–2017–0019, FMCSA–2017–0020, FMCSA–2018–0017, FMCSA–2019–0005, FMCSA–2019–0009, or FMCSA–2019–0011 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–1998–4334; FMCSA–1999–5578; FMCSA–2000–7363; FMCSA–2001–9258; FMCSA–2001–9561; FMCSA–2002–11714; FMCSA–2002–13411; FMCSA–2003–14223; FMCSA–2003–14504; FMCSA–2003–15268; FMCSA–2005–20560; FMCSA–2005–21254; FMCSA–2006–25246; FMCSA–2006–26066; FMCSA–2006–26653; FMCSA–2007–2663; FMCSA–2007–27333; FMCSA–2007–27515; FMCSA–2007–27897; FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2008–0340; FMCSA–2008–0398; FMCSA–2009–0054; FMCSA–2009–0086; FMCSA–2009–0121; FMCSA–2009–0154; FMCSA–2009–0291; FMCSA–2010–0082; FMCSA–2010–0187; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2010–0413; FMCSA–2011–0010; FMCSA–2011–0024; FMCSA–2011–0092; FMCSA–2011–0102; FMCSA–2011–0140; FMCSA–2012–0040; FMCSA–2012–0215; FMCSA–2012–0279; FMCSA–2012–0337; FMCSA–2013–0022; FMCSA–2013–0024; FMCSA–2013–0025; FMCSA–2013–0027; FMCSA–2013–0028; FMCSA–2013–0029; FMCSA–2013–0030; FMCSA–2014–0007; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2014–0298; FMCSA–2014–0302; FMCSA–2014–0304; FMCSA–2014–0305; FMCSA–2015–0048; FMCSA–2015–

0049; FMCSA–2015–0052; FMCSA–2015–0053; FMCSA–2015–0055; FMCSA–2015–0072; FMCSA–2016–0030; FMCSA–2016–0033; FMCSA–2016–0206; FMCSA–2016–0208; FMCSA–2016–0212; FMCSA–2016–0213; FMCSA–2016–0214; FMCSA–2017–0014; FMCSA–2017–0017; FMCSA–2017–0019; FMCSA–2017–0020; FMCSA–2018–0017; FMCSA–2019–0005; FMCSA–2019–0009; FMCSA–2019–0011), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *www.regulations.gov/,* insert the docket number, FMCSA–1998–4334, FMCSA–1999–5578, FMCSA–2000–7363, FMCSA–2001–9258, FMCSA–2001–9561, FMCSA–2002–11714, FMCSA–2002–13411, FMCSA–2003–14223, FMCSA–2003–14504, FMCSA–2003–15268, FMCSA–2005–20560, FMCSA–2005–21254, FMCSA–2006–25246, FMCSA–2006–26066, FMCSA–2006–26653, FMCSA–2007–2663, FMCSA–2007–27333, FMCSA–2007–27515, FMCSA–2007–27897, FMCSA–2008–0021, FMCSA–2008–0106, FMCSA–2008–0340, FMCSA–2008–0398, FMCSA–2009–0054, FMCSA–2009–0086, FMCSA–2009–0121, FMCSA–2009–0154, FMCSA–2009–0291, FMCSA–2010–0082, FMCSA–2010–0187, FMCSA–2010–0354, FMCSA–2010–0385, FMCSA–2010–0413, FMCSA–2011–0010, FMCSA–2011–0024, FMCSA–2011–0092, FMCSA–2011–0102, FMCSA–2011–0140, FMCSA–2012–0040, FMCSA–2012–0215, FMCSA–2012–0279, FMCSA–2012–0337, FMCSA–2013–0022, FMCSA–2013–0024, FMCSA–2013–0025, FMCSA–2013–0027, FMCSA–2013–0028, FMCSA–2013–0029, FMCSA–2013–0030, FMCSA–2014–0007, FMCSA–2014–0011, FMCSA–2014–0296, FMCSA–2014–0298, FMCSA–2014–0302, FMCSA–2014–0304, FMCSA–2014–0305, FMCSA–2015–0048, FMCSA–2015–0049, FMCSA–2015–0052, FMCSA–2015–0053, FMCSA–2015–0055, FMCSA–2015–0072, FMCSA–2016–0030, FMCSA–2016–0033, FMCSA–2016–0206, FMCSA–2016–0208, FMCSA–2016–0212, FMCSA–2016–0213, FMCSA–2016–0214, FMCSA–2017–0014, FMCSA–2017–0017, FMCSA–2017–0019, FMCSA–2017–0020, FMCSA–2018–0017, FMCSA–2019–0005, FMCSA–2019–0009, or FMCSA–2019–0011 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–1998–4334, FMCSA–1999–5578, FMCSA–2000–7363, FMCSA–2001–9258, FMCSA–2001–9561, FMCSA–2002–11714, FMCSA–2002–13411, FMCSA–2003–14223, FMCSA–2003–14504, FMCSA–2003–15268, FMCSA–2005–20560, FMCSA–2005–21254, FMCSA–2006–25246, FMCSA–2006–26066, FMCSA–2006–26653, FMCSA–2007–2663, FMCSA–2007–27333, FMCSA–2007–27515, FMCSA–2007–27897, FMCSA–2008–0021, FMCSA–2008–0106, FMCSA–2008–0340, FMCSA–2008–0398, FMCSA–2009–0054, FMCSA–2009–0086, FMCSA–2009–0121, FMCSA–2009–0154, FMCSA–2009–0291, FMCSA–2010–0082, FMCSA–2010–0187, FMCSA–2010–0354, FMCSA–2010–0385, FMCSA–2010–0413, FMCSA–2011–0010, FMCSA–2011–0024, FMCSA–2011–0092, FMCSA–2011–0102, FMCSA–2011–0140, FMCSA–2012–0040, FMCSA–2012–0215, FMCSA–2012–0279, FMCSA–2012–0337, FMCSA–2013–0022, FMCSA–2013–0024, FMCSA–2013–0025, FMCSA–2013–0027, FMCSA–2013–0028, FMCSA–2013–0029, FMCSA–2013–0030, FMCSA–2014–0007, FMCSA–2014–0011, FMCSA–2014–0296, FMCSA–2014–0298, FMCSA–2014–0302, FMCSA–2014–0304, FMCSA–2014–0305, FMCSA–2015–0048, FMCSA–2015–0049, FMCSA–2015–0052, FMCSA–2015–0053, FMCSA–2015–0055, FMCSA–2015–0072, FMCSA–2016–0030, FMCSA–2016–0033, FMCSA–2016–0206, FMCSA–2016–0208, FMCSA–2016–0212, FMCSA–2016–0213, FMCSA–2016–0214, FMCSA–2017–0014, FMCSA–2017–0017, FMCSA–2017–0019, FMCSA–2017–0020, FMCSA–2018–0017, FMCSA–2019–0005, FMCSA–2019–0009, or FMCSA–2019–0011 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

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 *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding vision found in 49 CFR 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

The 123 individuals listed in this notice have requested renewal of their exemptions from the vision standard in § 391.41(b)(10), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 123 applicants has satisfied the renewal conditions for obtaining an exemption from the vision standard (see 63 FR 66226, 64 FR 16517, 64 FR 27027, 64 FR 51568, 65 FR 45817, 65 FR 77066, 66 FR 17743, 66 FR 30502, 66 FR 33990, 66 FR 41654, 66 FR 41656, 66 FR 48504, 67 FR 15662, 67 FR 37907, 67 FR 76439, 68 FR 10298, 68 FR 10301, 68 FR 19596, 68 FR 19598, 68 FR 33570, 68 FR 35772, 68 FR 37197, 68 FR 44837, 68 FR 48989, 68 FR 54775, 69 FR 26206, 70 FR 7545, 70 FR 16886, 70 FR 17504, 70 FR 25878, 70 FR 30997, 70 FR 30999, 70 FR 33937, 70 FR 41811, 70 FR 42615, 70 FR 46567, 70 FR 53412, 71 FR 26602, 71 FR 63379, 72 FR 180, 72 FR 1051, 72 FR 7812, 72 FR 8417, 72 FR 9397, 72 FR 12666, 72 FR 18726, 72 FR 21313, 72 FR 25831, 72 FR 27624, 72 FR 28093, 72 FR 32703, 72 FR 32705, 72 FR 36099, 72 FR 39879, 72 FR 40359, 72 FR 40360, 72 FR 52419, 72 FR 62896, 73 FR 15568, 73 FR 27017, 73 FR 35198, 73 FR 48275, 73 FR 75803, 73 FR 78423, 74 FR 6209, 74 FR 6211, 74 FR 7097, 74 FR 11988, 74 FR 11991, 74 FR 15584, 74 FR 15586, 74 FR 19267, 74 FR 19270, 74 FR 20253, 74 FR 21427, 74 FR 23472, 74 FR 26461, 74 FR 26464, 74 FR 26466, 74 FR 28094, 74 FR 34074, 74 FR 34395, 74 FR 34630, 74 FR 34632, 74 FR 37295, 74 FR 41971, 74 FR 43221, 74 FR 48343, 74 FR 65842, 75 FR 9482, 75 FR 25918, 75 FR 27621, 75 FR 38602, 75 FR 39729, 75 FR 44051, 75 FR 47883, 75 FR 63257, 75 FR 72863, 75 FR 77492, 75 FR 77942, 75 FR 79083, 76 FR 1493, 76 FR 2190, 76 FR 4413, 76 FR 5425, 76 FR 9856, 76 FR 9865, 76 FR 12408, 76 FR 15361, 76 FR 17481, 76 FR 20076, 76 FR 21796, 76 FR 25762, 76 FR 25766, 76 FR 28125, 76 FR 29022, 76 FR 29026, 76 FR 32016, 76 FR 32017, 76 FR 34135, 76 FR 37168, 76 FR 37169, 76 FR 37173, 76 FR 37885, 76 FR 44082, 76 FR 44652, 76 FR 44653, 76 FR 49531, 76 FR 50318, 76 FR 53708, 76 FR 54530, 77 FR 10606, 77 FR 23799, 77 FR 27849, 77 FR 33558, 77 FR 36338, 77 FR 40945, 77 FR 46153, 77 FR 52381, 77 FR 60008, 77 FR 60010, 77 FR 64841, 77 FR 70534, 77 FR 71671, 77 FR 74273, 77 FR 74734, 78 FR 797, 78 FR 800, 78 FR 9772, 78 FR 11731, 78 FR 12813, 78 FR 12815, 78 FR 12822, 78 FR 16761, 78 FR 16762, 78 FR 16912, 78 FR 20376, 78 FR 22596, 78 FR 22602, 78 FR 24300, 78 FR 24798, 78 FR 26106, 78 FR 27281, 78 FR 29431, 78 FR 30954, 78 FR 32703, 78 FR 32708, 78 FR 34140, 78 FR 34141, 78 FR 34143, 78 FR 37270, 78 FR 41188, 78 FR 41975, 78 FR 46407, 78 FR 51268, 78 FR 51269, 78 FR 52602, 78 FR 56986, 78 FR 56993, 78 FR 57679, 78 FR 76705, 78 FR 78477, 79 FR 4531, 79 FR 14328, 79 FR 35220, 79 FR 38659, 79 FR 45868, 79 FR 46153, 79 FR 53514, 79 FR 56099, 79 FR 58856, 79 FR 59357, 79 FR 69985, 79 FR 70928, 79 FR 72754, 79 FR 73686, 79 FR 73687, 79 FR 73689, 80 FR 603, 80 FR 3305, 80 FR 3308, 80 FR 3723, 80 FR 8751, 80 FR 8927, 80 FR 12248, 80 FR 12254, 80 FR 14220, 80 FR 14223, 80 FR 15863, 80 FR 16500, 80 FR 16502, 80 FR 18696, 80 FR 20559, 80 FR 22773, 80 FR 25766, 80 FR 25768, 80 FR 26139, 80 FR 26320, 80 FR 29149, 80 FR 29152, 80 FR 29154, 80 FR 31636, 80 FR 31640, 80 FR 31957, 80 FR 33007, 80 FR 33009, 80 FR 33011, 80 FR 35699, 80 FR 36398, 80 FR 37718, 80 FR 40122, 80 FR 41547, 80 FR 41548, 80 FR 44185, 80 FR 44188, 80 FR 45573, 80 FR 48402, 80 FR 48404, 80 FR 48409, 80 FR 48411, 80 FR 48413, 80 FR 49302, 80 FR 50915, 80 FR 50917, 80 FR 53383, 80 FR 62161, 80 FR 62163, 80 FR 70060, 81 FR 15401, 81 FR 16265, 81 FR 45214, 81 FR 59266, 81 FR 60115, 81 FR 66726, 81 FR 70253, 81 FR 71173, 81 FR 72642, 81 FR 74494, 81 FR 81230, 81 FR 86063, 81 FR 90050, 81 FR 91239, 81 FR 96165, 81 FR 96180, 81 FR 96191, 81 FR 96196, 82 FR 12678, 82 FR 12683, 82 FR 13043, 82 FR 13048, 82 FR 13187, 82 FR 15277, 82 FR 17736, 82 FR 18818, 82 FR 18949, 82 FR 20962, 82 FR 22379, 82 FR 23712, 82 FR 26224, 82 FR 32919, 82 FR 33542, 82 FR 34564, 82 FR 35043, 82 FR 37499, 82 FR 47295, 82 FR 47296, 83 FR 4537, 83 FR 6919, 83 FR 28325, 83 FR 34661, 83 FR 40638, 83 FR 45750, 83 FR 53724, 83 FR 56137, 83 FR 56902, 84 FR 2311, 84 FR 2314, 84 FR 2326, 84 FR 10389, 84 FR 12665, 84 FR 16320, 84 FR 21393, 84 FR 21397, 84 FR 21401, 84 FR 23629, 84 FR 33801, 84 FR 47038, 84 FR 47045, 84 FR 47047, 84 FR 47057, 84 FR 52166). They have submitted evidence showing that the vision in the better eye continues to meet the requirement specified at § 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past 2 years indicates each applicant continues to meet the vision exemption requirements. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of September and are discussed below.

As of September 6, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following 115 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (63 FR 66226, 64 FR 16517, 65 FR 45817, 65 FR 77066, 66 FR 17743, 66 FR 30502, 66 FR 33990, 66 FR 41654, 66 FR 41656, 67 FR 15662, 67 FR 37907, 67 FR 76439, 68 FR 10298, 68 FR 10301, 68 FR 19596, 68 FR 19598, 68 FR 33570, 68 FR 35772, 68 FR 37197, 68 FR 44837, 68 FR 48989, 69 FR 26206, 70 FR 7545, 70 FR 16886, 70 FR 17504, 70 FR 25878, 70 FR 30997, 70 FR 30999, 70 FR 33937, 70 FR 41811, 70 FR 42615, 70 FR 46567, 71 FR 26602, 71 FR 63379, 72 FR 180, 72 FR 1051, 72 FR 7812, 72 FR 8417, 72 FR 9397, 72 FR 12666, 72 FR 18726, 72 FR 21313, 72 FR 25831, 72 FR 27624, 72 FR 28093, 72 FR 32703, 72 FR 32705, 72 FR 36099, 72 FR 40359, 72 FR 40360, 72 FR 62896, 73 FR 15568, 73 FR 27017, 73 FR 35198, 73 FR 48275, 73 FR 75803, 73 FR 78423, 74 FR 6209, 74 FR 6211, 74 FR 7097, 74 FR 11988, 74 FR 11991, 74 FR 15584, 74 FR 15586, 74 FR 19267, 74 FR 19270, 74 FR 20253, 74 FR 21427, 74 FR 23472, 74 FR 26461, 74 FR 26464, 74 FR 26466, 74 FR 28094, 74 FR 34074, 74 FR 34395, 74 FR 34630, 74 FR 34632, 74 FR 43221, 74 FR 65842, 75 FR 9482, 75 FR 25918, 75 FR 27621, 75 FR 38602, 75 FR 39729, 75 FR 44051, 75 FR 47883, 75 FR 63257, 75 FR 72863, 75 FR 77492, 75 FR 77942, 75 FR 79083, 76 FR 1493, 76 FR 2190, 76 FR 4413, 76 FR 5425, 76 FR 9856, 76 FR 9865, 76 FR 12408, 76 FR 15361, 76 FR 17481, 76 FR 20076, 76 FR 21796, 76 FR 25762, 76 FR 25766, 76 FR 28125, 76 FR 29022, 76 FR 29026, 76 FR 32016, 76 FR 32017, 76 FR 34135, 76 FR 37168, 76 FR 37169, 76 FR 37173, 76 FR 37885, 76 FR 44082, 76 FR 44652, 76 FR 44653, 76 FR 49531, 76 FR

50318, 76 FR 53708, 77 FR 10606, 77 FR 23799, 77 FR 27849, 77 FR 33558, 77 FR 36338, 77 FR 40945, 77 FR 46153, 77 FR 52381, 77 FR 60008, 77 FR 60010, 77 FR 64841, 77 FR 70534, 77 FR 71671, 77 FR 74273, 77 FR 74734, 78 FR 797, 78 FR 800, 78 FR 9772, 78 FR 11731, 78 FR 12813, 78 FR 12815, 78 FR 12822, 78 FR 16761, 78 FR 16762, 78 FR 16912, 78 FR 20376, 78 FR 22596, 78 FR 22602, 78 FR 24300, 78 FR 24798, 78 FR 26106, 78 FR 27281, 78 FR 29431, 78 FR 30954, 78 FR 32703, 78 FR 32708, 78 FR 34140, 78 FR 34141, 78 FR 34143, 78 FR 37270, 78 FR 41188, 78 FR 46407, 78 FR 51268, 78 FR 51269, 78 FR 52602, 78 FR 56993, 78 FR 57679, 78 FR 76705, 78 FR 78477, 79 FR 4531, 79 FR 14328, 79 FR 35220, 79 FR 38659, 79 FR 45868, 79 FR 46153, 79 FR 53514, 79 FR 56099, 79 FR 58856, 79 FR 59357, 79 FR 69985, 79 FR 70928, 79 FR 72754, 79 FR 73686, 79 FR 73687, 79 FR 73689, 80 FR 603, 80 FR 3305, 80 FR 3308, 80 FR 3723, 80 FR 8751, 80 FR 8927, 80 FR 12248, 80 FR 12254, 80 FR 14220, 80 FR 14223, 80 FR 15863, 80 FR 16500, 80 FR 16502, 80 FR 18696, 80 FR 20559, 80 FR 22773, 80 FR 25766, 80 FR 25768, 80 FR 26139, 80 FR 26320, 80 FR 29149, 80 FR 29152, 80 FR 29154, 80 FR 31636, 80 FR 31640, 80 FR 31957, 80 FR 33007, 80 FR 33009, 80 FR 33011, 80 FR 35699, 80 FR 36398, 80 FR 37718, 80 FR 40122, 80 FR 41547, 80 FR 41548, 80 FR 44185, 80 FR 44188, 80 FR 45573, 80 FR 48404, 80 FR 48409, 80 FR 48413, 80 FR 50917, 80 FR 62161, 80 FR 62163, 80 FR 70060, 81 FR 15401, 81 FR 16265, 81 FR 45214, 81 FR 59266, 81 FR 60115, 81 FR 66726, 81 FR 70253, 81 FR 71173, 81 FR 72642, 81 FR 74494, 81 FR 81230, 81 FR 86063, 81 FR 90050, 81 FR 91239, 81 FR 96165, 81 FR 96180, 81 FR 96191, 81 FR 96196, 82 FR 12678, 82 FR 12683, 82 FR 13043, 82 FR 13048, 82 FR 13187, 82 FR 15277, 82 FR 17736, 82 FR 18818, 82 FR 18949, 82 FR 20962, 82 FR 22379, 82 FR 23712, 82 FR 26224, 82 FR 32919, 82 FR 33542, 82 FR 34564, 82 FR 35043, 82 FR 37499, 82 FR 47295, 82 FR 47296, 83 FR 4537, 83 FR 6919, 83 FR 28325, 83 FR 34661, 83 FR 40638, 83 FR 45750, 83 FR 53724, 83 FR 56137, 83 FR 56902, 84 FR 2311, 84 FR 2314, 84 FR 2326, 84 FR 10389, 84 FR 12665, 84 FR 16320, 84 FR 21393, 84 FR 21397, 84 FR 21401, 84 FR 23629, 84 FR 33801, 84 FR 47038, 84 FR 47045, 84 FR 47047, 84 FR 47057, 84 FR 52166):

Stanley C. Anders (SD)
Joseph W. Bahr (NJ)
Kreis C. Baldridge (TN)
Timothy D. Beaulier (MI)
Roosevelt Bell, Jr. (NC)
Rex A. Botsford (MI)
William L. Brady (KS)
Ryan L. Brown (IL)
Dale E. Bunke (ID)
Danny F. Burnley (KY)
Joseph L. Butler (IN)
Shawn M. Carroll (OK)
Bernabe V. Cerda (TX)
Paul M. Christina (PA)
Randy A. Cimei (IL)
Daniel G. Cohen (VT)
Gary G. Colby (UT)
Joseph W. Colecchi (PA)
Sean R. Conorman (MI)
William T. Costie (NY)
Jeffrey W. Cotner (OR)
Kenneth D. Craig (VA)
Edwin P. Davis (OR)
Edwin T. Donaldson (PA)
Everett A. Doty (AZ)
Rex A. Dyer (VT)
John A. Edison (GA)
Paul E. Emmons (RI)
James G. Etheridge (TX)
Randy L. Fales (MN)
Ray A. Fields (KS)
Dennis E. Fisher (NY)
Paul T. Fisher (MA)
Steven C. Fox (NC)
Steve L. Frisby (CA)
Patrick J. Goebel (IA)
Wladyslaw Gogola (IL)
Antonio Gomez (PA)
Timothy M. Good (MI)
Sanford L. Goodwin (TX)
Johnny J. Gowdy (MS)
Randy N. Grandfield (VT)
Edward J. Grant (IL)
Robert E. Graves (NE)
Samuel R. Graziano (PA)
Rocky D. Gysberg (MN)
Gary D. Hallman (AL)
Kenneth L. Handy (IA)
Paul R. Harpin (AZ)
Britt D. Hazelwood (IL)
George F. Hernandez, Jr. (AZ)
Andrew F. Hill (TX)
Wade M. Hillmer (MN)
Charlie E. Hoggard (TX)
David A. Inman (IN)
Donald M. Jenson (SD)
Daryl A. Jester (DE)
John T. Johnson (NM)
William D. Johnson (OK)
Christopher J. Kane (VT)
Christopher M. Keen (KS)
James J. Keranen (MI)
Lester H. Killingsworth (TX)
Laine Lewin (MN)
Craig M. Mahaffey (OH)
Michael G. Martin (CT)
Joe A. McIlroy (NY)
Luther A. McKinney (VA)
Gary G. McKown (WV)
Raymond W. Meier (WA)
Carlos A. Mendez-Castellon (VA)
Brian P. Millard (SC)
Jeffrey T. Molosz (IL)
Daniel R. Murphy (WI)
Warren J. Nyland (MI)
Jeffrey L. Olson (MN)
Mark A. Omps (WV)
Jerry D. Paul (OK)
Johnny A. Peery (MD)
David Perkins (NY)
Juan C. Puente (TX)
Donie L. Rhoads (MT)
Robert E. Richards (ME)
James R. Robinette (VA)
Steven D. Scharber (MN)
Mark A. Schlesselman (OH)
Raymond Sherrill (PA)
James Smentkowski (NJ)
Dennis J. Smith (CO)
Myron A. Smith (MN)
Harry Smith, Jr. (NC)
Francis A. St. Pierre (NH)
Jerry M. Stearns (AR)
Donald E. Stone (VA)
Thomas E. Summers, Sr. (OH)
Warren Supulski (NC)
Paul C. Swanson (IL)
Grover C. Taylor (VA)
Jon C. Thompson (TX)
Anthony J. Thornburg (MI)
Donald R. Torbett (IA)
Wesley E. Turner (TX)
Eric M. Turton (NY)
Donald A. Uplinger II (OH)
Mona J. Van Krieken (OR)
Lynn D. Veach (IA)
Scott Wallbank (MA)
Roy J. Ware (GA)
Donald L. Weston (PA)
Jeff L. Wheeler (IA)
Theodore A. White (PA)
Wayne A. Whitehead (NY)
Cameron R. Whitford (NY)
David Wiebe (TX)
Paul A. Wolfe (OH)

The drivers were included in docket numbers FMCSA–1998–4334, FMCSA–2000–7363, FMCSA–2001–9258, FMCSA–2001–9561, FMCSA–2002–11714, FMCSA–2002–13411, FMCSA–2003–14223, FMCSA–2003–14504, FMCSA–2003–15268, FMCSA–2005–20560, FMCSA–2005–21254, FMCSA–2006–25246, FMCSA–2006–26066, FMCSA–2006–26653, FMCSA–2007–2663, FMCSA–2007–27333, FMCSA–2007–27515, FMCSA–2008–0021, FMCSA–2008–0106, FMCSA–2008–0340, FMCSA–2008–0398, FMCSA–2009–0054, FMCSA–2009–0086, FMCSA–2009–0121, FMCSA–2009–0291, FMCSA–2010–0082, FMCSA–2010–0187, FMCSA–2010–0354, FMCSA–2010–0385, FMCSA–2010–0413, FMCSA–2011–0010, FMCSA–2011–0024, FMCSA–2011–0092, FMCSA–2011–0102, FMCSA–2011–0140, FMCSA–2012–0040, FMCSA–2012–0215, FMCSA–2012–0279, FMCSA–2012–0337, FMCSA–2013–0022, FMCSA–2013–0024, FMCSA–2013–0025, FMCSA–2013–0027, FMCSA–2013–0028, FMCSA–2013–0029, FMCSA–2014–0007, FMCSA–2014–0011, FMCSA–2014–0296, FMCSA–2014–0298, FMCSA–2014–

0302, FMCSA–2014–0304, FMCSA–2014–0305, FMCSA–2015–0048, FMCSA–2015–0049, FMCSA–2015–0052, FMCSA–2015–0053, FMCSA–2015–0055, FMCSA–2015–0072, FMCSA–2016–0030, FMCSA–2016–0033, FMCSA–2016–0206, FMCSA–2016–0208, FMCSA–2016–0212, FMCSA–2016–0213, FMCSA–2016–0214, FMCSA–2017–0014, FMCSA–2017–0017, FMCSA–2017–0019, FMCSA–2017–0020, FMCSA–2018–0017, FMCSA–2019–0005, FMCSA–2019–0009, and FMCSA–2019–0011. Their exemptions are applicable as of September 6, 2021 and will expire on September 6, 2023.

As of September 7, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following individual has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (76 FR 37169, 76 FR 50318, 78 FR 78477, 80 FR 50915, 83 FR 4537, 84 FR 47038):

Charles E. Carter (MI)

The driver was included in docket number FMCSA–2011–0140. The exemption is applicable as of September 7, 2021 and will expire on September 7, 2023.

As of September 13, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following two individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (72 FR 39879, 72 FR 52419, 74 FR 41971, 76 FR 54530, 78 FR 78477, 80 FR 48402, 83 FR 4537, 84 FR 47038):

Ray C. Johnson (AR); and Joshua R. Perkins (ID)

The drivers were included in docket number FMCSA–2007–27897. Their exemptions are applicable as of September 13, 2021 and will expire on September 13, 2023.

As of September 16, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following two individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (78 FR 41975, 78 FR 56986, 80 FR 48411, 83 FR 4537, 84 FR 47038):

Carl H. Block (NY); and Vincent E. Marsee, Sr. (NC)

The drivers were included in docket number FMCSA–2013–0030. Their exemptions are applicable as of September 16, 2021 and will expire on September 16, 2023.

As of September 22, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following individual has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (74 FR 37295, 74 FR 48343, 76 FR 53708, 78 FR 78477, 80 FR 49302, 83 FR 4537, 84 FR 47038):

Samuel A. Miller (IN)

The driver was included in docket number FMCSA–2009–0154. The exemption is applicable as of September 22, 2021 and will expire on September 22, 2023.

As of September 23, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following two individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (64 FR 27027, 64 FR 51568, 66 FR 48504, 68 FR 19598, 68 FR 33570, 68 FR 54775, 70 FR 53412, 72 FR 62896, 74 FR 43221, 76 FR 53708, 78 FR 78477, 80 FR 53383, 83 FR 4537, 84 FR 47038):

Weldon R. Evans (OH); and Orasio Garcia (TX)

The drivers were included in docket numbers FMCSA–1999–5578 and FMCSA–2003–14504. Their exemptions are applicable as of September 23, 2021 and will expire on September 23, 2023.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must undergo an annual physical examination (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a certified medical examiner (ME), as defined by § 390.5, who attests that the driver is otherwise physically qualified under § 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the ME at the time of the annual medical examination; and (3) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file or keep a copy of his/her driver's qualification if he/her is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 123 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the vision requirement in § 391.41(b)(10), subject to the requirements cited above. In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–16540 Filed 8–3–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, August 24, 2021 and Wednesday, August 25, 2021.

FOR FURTHER INFORMATION CONTACT: Gilbert Martinez at 1–888–912–1227 or (737) 800–4060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Tuesday, August 24, 2021, from 1:30pm to 3:30pm Eastern Time and Wednesday, August 25, 2021, from 1:30pm to 3:30pm Eastern Time. The public is invited to make oral comments or submit written statements for consideration. For more information please contact Gilbert Martinez at 1–888–912–1227 or (737–800–4060), or write TAP Office 3651 S. IH–35, STOP 1005 AUSC, Austin, TX 78741, or post comments to the website: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the

IRS and other TAP related topics. Public input is welcomed.

Dated: July 30, 2021.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2021–16640 Filed 8–3–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Cost-Based and Inter-Agency Billing Rates for Medical Care or Services Provided by the Department of Veterans Affairs for Fiscal Year 2022

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: This document updates the Cost-Based and Inter-Agency billing rates for medical care or services provided by the U.S. Department of Veterans Affairs (VA) furnished in certain circumstances.

DATES: The rates set forth herein are effective October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Debra Vatthauer, Office of Community Care, Revenue Operations, Payer Relations and Services, Rates and Charges (13RO1), Veterans Health Administration, Department of Veterans Affairs, 128 Bingham Road, Suite 1000, Asheville, NC 28806; telephone: 608–821–7346 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: VA's methodology for computing Cost-Based and Inter-Agency rates for medical care or services provided by VA is set forth in section 17.102(h) of title 38 Code of Federal Regulations (CFR). Two sets of rates are obtained by applying this methodology, Cost-Based and Inter-Agency.

Cost-Based rates apply to medical care and services that are provided by VA under 38 CFR 17.102(a), (b), (d) and (g), respectively, in the following circumstances:

- In error or based on tentative eligibility;
- In a medical emergency;
- To pensioners of allied nations; and
- For research purposes in circumstances under which the medical care appropriation shall be reimbursed from the research appropriation.

Inter-Agency rates apply to medical care and services that are provided by VA under § 17.102(c) and (f), respectively, in the following circumstances when the care or services provided are not covered by any applicable sharing agreement in accordance with § 17.102(e):

- To beneficiaries of the Department of Defense or other Federal agencies; and
- To military retirees with chronic disability.

The calculations for the Cost-Based and Inter-Agency rates are the same with two exceptions. Inter-Agency rates are all-inclusive and are not broken down into three components (*i.e.,* Physician; Ancillary; and Nursing, Room and Board), and do not include standard fringe benefit costs that cover Government employee retirement, disability costs, and return on fixed assets.

The following table depicts the Cost-Based and Inter-Agency rates that are effective October 1, 2021 and will remain in effect until the next fiscal year **Federal Register** update. These rates supersede those established by the **Federal Register** notice published on July 28, 2020, at 85 FR 45471.

	Cost-based rates	Inter-agency rates
A. Hospital Care per inpatient day		
General Medicine:		
All Inclusive Rate	$5,466	$5,318
Physician	654	
Ancillary	1,424	
Nursing Room and Board	3,388	
Neurology:		
All Inclusive Rate	5,127	4,981
Physician	751	
Ancillary	1,354	
Nursing Room and Board	3,022	
Rehabilitation Medicine:		
All Inclusive Rate	3,963	3,846
Physician	450	
Ancillary	1,211	
Nursing Room and Board	2,302	
Blind Rehabilitation:		
All Inclusive Rate	2,933	2,843
Physician	236	
Ancillary	1,457	
Nursing Room and Board	1,240	
Spinal Cord Injury:		
All Inclusive Rate	3,548	3,443
Physician	440	
Ancillary	893	
Nursing Room and Board	2,215	
Surgery:		
All Inclusive Rate	9,756	9,490
Physician	1,075	
Ancillary	2,959	
Nursing Room and Board	5,722	
General Psychiatry:		
All Inclusive Rate	2,875	2,788
Physician	271	
Ancillary	453	
Nursing Room and Board	2,151	
Substance Abuse (Alcohol and Drug Treatment):		
All Inclusive Rate	2,744	2,663

	Cost-based rates	Inter-agency rates
Physician	262	
Ancillary	635	
Nursing Room and Board	1,847	
Psychosocial Residential Rehabilitation Program:		
All Inclusive Rate	358	348
Physician	23	
Ancillary	38	
Nursing Room and Board	297	
Intermediate Medicine:		
All Inclusive Rate	3,269	3,179
Physician	161	
Ancillary	480	
Nursing Room and Board	2,628	
Poly-trauma Inpatient:		
All Inclusive Rate	3,936	3,805
Physician	447	
Ancillary	1,202	
Nursing Room and Board	2,287	
B. Nursing Home Care, Per Day		
All Inclusive Rate	1,750	1,698
Physician	54	
Ancillary	237	
Nursing Room and Board	1,459	
C. Outpatient Medical Treatments		
Outpatient Visit (to include Ineligible Emergency Dental Care)	506	493
Outpatient Physical Medicine & Rehabilitation Service Visit	347	336
Outpatient Poly-trauma/Traumatic Brain Injury	678	660

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on July 30, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulation Development Coordinator Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2021–16627 Filed 8–3–21; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 86 Wednesday,

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 416, 419, et al.

45 CFR Part 180

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 416, 419, and 512

Office of the Secretary

45 CFR Part 180

[CMS–1753–P]

RIN 0938–AU43

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), Depatment of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2022 based on our continuing experience with these systems. In this proposed rule, we describe the proposed 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. Also, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program, update Hospital Price Transparency requirements, and update and refine the design of the Radiation Oncology Model. Finally, this proposed rule includes a Request for Information (RFI) focusing on the health and safety standards, quality measures and reporting requirements, and payment policies for Rural Emergency Hospitals (REHs), a new Medicare provider type. The RFI will be used to inform future rulemaking for REHs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 17, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1753–P when commenting on the issues in this proposed rule. 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–1753–P, P.O. Box 8010, 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–1753–P, 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: 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 at *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Cyra Duncan via email *Cyra.Duncan@cms.hhs.gov*.

Blood and Blood Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Cancer Hospital Payments, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email at *Chuck.Braver@cms.hhs.gov*.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Au'Sha Washington via email at *AuSha.Washington@cms.hhs.gov*.

Comprehensive APCs (C–APCs), contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

Hospital Inpatient Quality Reporting Program—Administration Issues, contact Julia Venanzi, *julia.venanzi@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Shaili Patel via email *Shaili.Patel@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Janis Grady via email *Janis.Grady@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

Hospital Price Transparency, contact the Hospital Price Transparency email box at *PriceTransparencyHospitalCharges@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov*, or Allison Bramlett via email *Allison.Bramlett@cms.hhs.gov*, Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Abigail Cesnik at *Abigail.Cesnik@cms.hhs.gov*.

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule), contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

OPPS Brachytherapy, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

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 at *Erick.Chuang@cms.hhs.gov*, or Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*, or Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*, or Gil Ngan via email at *Gil.Ngan@cms.hhs.gov*, or Cory Duke via email at *Cory.Duke@cms.hhs.gov*, or Au'Sha

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OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at *NewTechAPCapplications@cms.hhs.gov*.

OPPS Packaged Items/Services, contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or Cory Duke via email at *Cory.Duke@cms.hhs.gov*.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at *DevicePTapplications@cms.hhs.gov*.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at *Marina.Kushnirova@cms.hhs.gov*.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov*.

Rural Hospital Payments, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Skin Substitutes, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Supervision of Outpatient Therapeutic Services in Hospitals and CAHs, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

RO Model, contact *RadiationTherapy@cms.hhs.gov* or at 844–711–2664, Option 5.

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. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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/Hospital-Outpatient-Regulations-and-Notices*.

The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices*.

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we propose to update 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, 2022. 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, the relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This proposed rule also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

2. Summary of the Major Provisions

- *OPPS Update:* For 2022, we propose to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.3 percent. This increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.5 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a proposed productivity adjustment of 0.2 percentage point. 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 calendar year (CY) 2022 would be approximately $82.704 billion, an increase of approximately $10.757 billion compared to estimated CY 2021 OPPS payments.

We propose to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services.

- *Data used in CY 2022 OPPS/ASC Ratesetting:* To set CY 2022 OPPS and ASC payment rates, we would normally use the most updated claims and cost report data available. However, because the CY 2020 claims data includes services furnished during the COVID–19 PHE, which significantly affected outpatient service utilization, we have determined that CY 2019 data would better approximate expected CY 2022 outpatient service utilization than CY 2020 data. As a result, we are proposing to utilize CY 2019 data to set CY 2022 OPPS and ASC payment rates.
- *Partial Hospitalization Update:* For the CY 2022 OPPS/ASC proposed rule, CMS is proposing to use the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs, consistent with existing methodology, but with a cost floor that would maintain the per diem costs finalized in CY 2021. CMS is also proposing to use CY 2019 claims and cost report data for each provider type. This proposal is consistent with a broader CY 2022 OPPS ratesetting proposal to use claims and cost report data prior to the PHE.
- *Changes to the Inpatient Only (IPO) List:* For 2022, we propose to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 against our longstanding criteria for removal, we propose to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022. CMS is also proposing to codify in regulation the five longstanding criteria used to determine whether a procedure or service should be removed from the IPO list. In addition, we solicit comment on several policy modifications including whether CMS should maintain the longer-term objective of eliminating the IPO list or maintain the IPO list but continue to systematically scale the list back so that inpatient only designations are consistent with current standards of practice.
- *Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule):* For CY 2022,

we propose to exempt procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on or January 1, 2021, from site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC–QIO) referrals to Recovery Audit Contractor (RAC) for persistent noncompliance with the 2-midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service) for a time period of 2 years.

• 340B-*Acquired Drugs:* We propose to continue our current policy of paying an adjusted amount of ASP minus 22.5 percent for drugs and biologicals acquired under the 340B program. We are proposing to continue to exempt Rural SCHs, PPS-exempt cancer hospitals and children's hospitals from our 340B payment policy.

• *Device Pass-Through Payment Applications:* For CY 2022, we received eight applications for device pass-through payments. One of these applications (the Shockwave C² Coronary Intravascular Lithotripsy (IVL) catheter) received preliminary approval for pass-through payment status through our quarterly review process. We are soliciting public comment on all eight of these applications and final determinations on these applications will be made in the CY 2022 OPPS/ASC final rule.

• *Equitable Adjustment for Device Category, Drugs, and Biologicals with Expiring Pass-through Status:* As a result of our proposal to use CY 2019 claims data, rather than CY 2020 claims data, to inform CY 2022 ratesetting, we are proposing to use our equitable adjustment authority under 1833(t)(2)(E) to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass-through payment status will expire between December 31, 2021 and September 30, 2022.

• *Cancer Hospital Payment Adjustment:* For 2022, we propose to continue to provide additional payments to cancer hospitals so that a 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 propose that a target PCR of 0.89 would be used to determine the CY 2022 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 0.89 for each cancer hospital.

• *ASC Payment Update:* For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. Using the hospital market basket methodology, for CY 2022, we propose to increase payment rates under the ASC payment system by 2.3 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This proposed increase is based on a hospital market basket percentage increase of 2.5 percent reduced by a proposed productivity adjustment of 0.2 percentage point. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2022 would be approximately 5.16 billion, a decrease of approximately 20 million compared to estimated CY 2021 Medicare payments.

• *ASC Payment Policy for Non-Opioid Pain Management Drugs and Biologicals under Section 6082 of the SUPPORT Act (Section 1833(t)(22) of the Social Security Act):* Under section 1833(t)(22)(A) of the Act, the Secretary was required to conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. Section 1833(t)(22)(A)(ii) provides that the Secretary may, as the Secretary determines appropriate, conduct subsequent reviews of such payment.

In accordance with our review, for CY 2022, we are proposing to continue to pay separately for two drugs currently receiving separate payment in the ASC setting as non-opioid pain management drugs that function as surgical supplies. For CY 2022, we propose to modify the current non-opioid pain management payment policy and regulatory text to require that evidence-based non opioid alternatives for pain management must have Food and Drug Administration (FDA) approval, an FDA-approved indication for pain management or analgesia, and for the drugs and biologicals to have a per-day cost in excess of the OPPS drug packaging threshold, which is proposed at $130 for CY 2022 and described in section V.B.1.a., to qualify under this policy. Further, we are soliciting comment on potential additional requirements the Secretary should consider establishing for this policy as well as whether any additional products meet the proposed criteria for CY 2022.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2022, we are proposing to re-adopt the ASC Covered Procedures List (CPL) criteria that were in effect in CY 2020 and to remove 258 of the 267 procedures that were added to the ASC CPL in CY 2021. We are requesting comments on whether any of the 258 procedures meet the CY 2020 criteria that we are proposing to reinstate. We are also proposing to change the notification process adopted in CY 2021 to a nomination process, under which stakeholders could nominate procedures they believe meet the requirements to be added to the ASC CPL. The formal nomination process would begin in CY 2023.

Hospital Outpatient Quality Reporting (OQR) Program: For the Hospital OQR Program, we are proposing changes for the CY 2023, CY 2024, CY 2025, and CY 2026 payment determinations and subsequent years. For the Hospital OQR Program measure set, we are proposing to: (1) Remove the OP–02: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival measure beginning with the CY 2025 payment determination; (2) remove the OP–03: Median Time to Transfer to Another Facility for Acute Coronary Intervention measure beginning with the CY 2025 payment determination; (3) adopt the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with the CY 2024 payment determination; (4) adopt the Breast Screening Recall Rates measure beginning with the CY 2023 payment determination; (5) adopt the ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM) beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination; (6) make voluntary the reporting of the OP–37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based measures beginning with the CY 2023 reporting period and mandatory beginning with the CY 2024 reporting period/CY 2026 payment determination; and (7) make mandatory the reporting of the OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure beginning with the CY 2025 payment determination. In addition, we are proposing data submission

requirements for the OAS CAHPS Survey-based measures and the COVID–19 Vaccination Coverage Among HCP measure. Similarly, we are proposing data submission and certification requirements for eCQMs and expanding our Extraordinary Circumstances Exemption (ECE) policy to these measures.

Beginning with the CY 2024 payment determination, we are proposing three updates to our validation requirements by proposing to: (1) Use electronic file submissions for chart-abstracted measure medical record requests; (2) change the chart validation requirements and methods; and (3) update the targeting criteria. We are also requesting comment from stakeholders on: (1) The potential future development and inclusion of a patient-reported outcomes measure following elective total hip and/or total knee arthroplasty (THA/TKA); (2) the possibility of expanding our current disparities methods to include reporting by race and ethnicity; and (3) the possibility of hospital collection of standardized demographic information for quality reporting and measure stratification. We are also requesting feedback across programs on potential actions and priority areas that would enable the continued transformation of our quality measurement toward greater digital capture of data and use of the FHIR standard.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program, we are proposing changes for the CY 2024, CY 2025, and CY 2026 payment determinations and subsequent years. For the ASCQR Program measure set, we are proposing to: (1) Adopt the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 payment determination; (2) resume data collection for four measures beginning with the CY 2025 payment determination: (a) ASC–1: Patient Burn; (b) ASC–2: Patient Fall; (c) ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and (d) ASC–4: All-Cause Hospital Transfer/Admission; (3) require the ASC–11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure beginning with the CY 2025 payment determination; and (4) require the ASC–15a-e: OAS CAHPS Survey-based measures with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination. In addition, we are proposing data submission requirements for the OAS CAHPS Survey-based measures and the COVID–19 Vaccination Coverage Among HCP measure.

We are requesting stakeholder comment on: (1) The potential future development and inclusion of a patient-reported outcomes measure following elective THA/TKA; (2) potential measurement approaches or social risk factors that influence health disparities in the ASC setting; and (3) the future inclusion of a measure to assess pain management surgical procedures performed in ASCs. In this proposed rule, we are also requesting feedback across programs on potential actions and priority areas that would enable the continued transformation of our quality measurement toward greater digital capture of data and use of the FHIR standard.

• *Hospital Inpatient Quality Reporting (IQR) Program Update:* In this proposed rule, we are requesting information from stakeholders on potential measure updates on reporting and submission requirements for the Safe Use of Opioids—Concurrent Prescribing eCQM.

• *Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges:* We are proposing to amend several hospital price transparency policies codified at 45 CFR part 180 in order to encourage compliance. We are proposing to: (1) Increase the amount of the penalties for noncompliance through the use of a proposed scaling factor based on hospital bed count; (2) deem state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180; and (3) prohibit certain conduct that we have concluded are barriers to accessing the standard charge information. In addition, we clarify the expected output of hospital online price estimator tools when hospitals choose to use an online price estimator tool in lieu of posting its standard charges for the required shoppable services in a consumer-friendly format. Finally, we seek comment on a variety of issues that we may consider in future rulemaking, including improving standardization of the data disclosed by hospitals.

• *Request for Information on Rural Emergency Hospitals (REHs):*

Congress enacted section 125 of the Consolidated Appropriations Act (CAA) of 2021, which establishes REHs as a new provider type. In accordance with the statutory requirements in the CAA, REHs will provide emergency department services, observation care, and, at the election of the REH, other medical and health services on an outpatient basis, as specified by the Secretary through rulemaking. Additionally, REHs must not provide acute care inpatient services, with the exception of skilled nursing facility services furnished in a distinct part unit. The REH must have a staffed emergency department 24 hours a day, 7 days a week, with staffing requirements similar to those for Critical Access Hospitals (CAHs). The CAA provides that the statutory provisions governing Medicare payment to REHs shall apply to items and services furnished on or after January 1, 2023. We are seeking public comment via a Request for Information on the health and safety standards, payment policies, the REH enrollment process, and quality measures and reporting requirements for REHs to inform our policy making as we establish this new provider type.

• *Radiation Oncology Model (RO Model):* Section 133 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260), enacted on December 27, 2020, included a provision that prohibits the RO Model from beginning before January 1, 2022. This law supersedes the RO Model delayed start date established in the CY 2021 OPPS/ASC final rule. In this proposed rule, we are proposing provisions related to the additional delayed implementation due to the CAA, 2021, as well as modifications to certain RO Model policies not related to the delay. These proposals if finalized would necessitate modifying 42 CFR 512.205, 512.210, 512.217, 512.220, 512.230, 512.240, 512.245, 512.250, 512.255, 512.275, 512.280, and 512.285 and add 42 CFR 512.292 and 512.294.

• *Comment Solicitation on Temporary Policies for the PHE for COVID–19:* In response to the COVID–19 pandemic, CMS undertook emergency rulemaking to implement a number of flexibilities to address the pandemic, such as preventing spread of the infection and supporting diagnosis of COVID–19. While many of these flexibilities will expire at the conclusion of the PHE, we are seeking comment on whether there are certain policies that should be made permanent. Specifically, we are seeking comment on services furnished by hospital staff to beneficiaries in their homes through use of communication technology, direct supervision when the supervising practitioner is available through two-way, audio/video communication technology, and code and payment for COVID–19 specimen collection.

• *Changes to Beneficiary Coinsurance for Colorectal Cancer Screening Test:* Section 122 of the Consolidated Appropriations Act (CAA) of 2021 amends section 1833(a) of the Act to

offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We propose that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy could be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of determining the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter.

3. Summary of Costs and Benefit

In sections XXIV. and XXV. of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table U1 in section XXIV.B of this proposed rule displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2021 compared to all estimated OPPS payments in CY 2020. We estimate that the policies in this proposed rule would result in a 1.8 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2021, including beneficiary cost-sharing, to the approximately 3,662 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately $1.3 billion compared to CY 2020 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 1.6 percent increase in CY 2021 payments to CMHCs relative to their CY 2020 payments.

b. Impacts of the Proposed Updated Wage Indexes

We estimate that our proposed update of the wage indexes based on the FY 2022 IPPS proposed rule wage indexes would result in no change for urban hospitals under the OPPS and no change 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 proposed rule.

c. Impacts of the Proposed Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2022 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not proposing to make any change in policies for determining the rural hospital payment adjustments. While we propose to implement the reduction to the cancer hospital payment adjustment for CY 2022 required by section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act, the target payment-to-cost ratio (PCR) for CY 2021 is 0.89, equivalent to the 0.89 target PCR for CY 2021, and therefore has no budget neutrality adjustment.

d. Impacts of the Proposed OPD Fee Schedule Increase Factor

For the CY 2021 OPPS/ASC, we propose to establish an OPD fee schedule increase factor of 2.3 percent and apply that increase factor to the conversion factor for CY 2021. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase in payments of approximately 2.3 percent and that rural hospitals would experience an increase in payments of 2.3 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals would experience an increase in payments of 2.5 percent, minor teaching hospitals would experience an increase in payments of 2.3 percent, and major teaching hospitals would experience an increase in payments of 2.2 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 2.3 percent in payments, while hospitals with government ownership would experience an increase of 2.4 percent in payments. We estimate that hospitals with proprietary ownership would experience an increase of 2.5 percent in payments.

e. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list 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 2022 payment rates, compared to estimated CY 2021 payment rates, generally ranges between an increase of 2 and 4 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to ASC payment rates would increase payments by $90 million under the ASC payment system in CY 2022.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the 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; 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; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), enacted on March 27, 2020; and the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020.

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 proposed rule. 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, as required by 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 are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care 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, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, 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 Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) 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;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- 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 20, 2020, for a 2-year period.

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/AdvisoryPanelonAmbulatoryPayment ClassificationGroups.html*.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 31, 2020. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and 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). In CY 2018, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (83 FR 3715). As published in this notice, CMS is accepting nominations on a continuous basis.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to 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 workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 31, 2020, meeting that the subcommittees continue. We accepted this recommendation.

Discussions of the other recommendations made by the Panel at the August 31, 2020 Panel meeting, namely APC assignments for certain CPT codes, a comprehensive APC for skin substitute products, a comprehensive APC for autologous hematopoietic stem cell transplantation, and packaging policies, were discussed in relevant specific sections in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85866). 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 on the CY 2020 OPPS/ASC Final Rule With Comment Period

We received approximately 32 timely pieces of correspondence on the CY 2021 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on December 2, 2020 (85 FR 85866), most of which were

outside of the scope of the final rule. In-scope comments related to 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).

II. Proposed Updates Affecting OPPS Payments

A. Proposed Recalibration of APC Relative Payment Weights

1. Database Construction

a. Use of CY 2019 Data in the CY 2022 OPPS Ratesetting

We primarily use two data sources in OPPS ratesetting: Claims data and cost report data. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available full year of claims data would be 2 years prior to the calendar year that is the subject of the rulemaking. As discussed in further detail in Section X.E. of this CY 2022 OPPS/ASC proposed rule, given our concerns with CY 2020 data as a result of the COVID–19 PHE, in general, we are proposing to use CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS.

b. 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.

For the CY 2022 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2022, and before January 1, 2023 (CY 2022), using the same basic methodology that we described in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85873), using CY 2019 claims data. That is, we propose to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2022, we began with approximately 180 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, 2019, and before January 1, 2020, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 93 million final action claims to develop the proposed CY 2022 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 this proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Addendum N to this proposed rule (which is available via the internet on the CMS website) includes the proposed list of bypass codes for CY 2022. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2019 and, therefore, includes codes that were in effect in CY 2019 and used for billing. We propose to retain deleted bypass codes on the proposed CY 2022 bypass list because these codes existed in CY 2019 and were covered OPD services in that period, and CY 2019 claims data were used to calculate proposed CY 2022 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 are identified by asterisks (*) in the third column of Addendum N to the proposed rule. HCPCS codes that we propose to add for CY 2022 are identified by asterisks (*) in the fourth column of Addendum N.

c. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For 2022, we propose 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 2022 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 2019 claims data by comparing these claims data to hospital cost reports available for the CY 2021 OPPS/ASC final rule with comment period ratesetting, which, in most cases, are from CY 2019. For the proposed CY 2022 OPPS payment rates, we used the set of CY 2019 claims processed through June 30, 2020. 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. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2019 (the year of claims data we used to calculate the proposed CY 2022 OPPS payment rates) and updates to the NUBC 2020 Data Specifications Manual. 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*.

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 this proposed rule.

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 comments we received from our CY 2014 OPPS/ASC proposed rule, we finalized a policy in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847) 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. As finalized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), beginning in CY 2021, we use all claims with valid CT and MRI cost center CCRs, including those that use a ''square feet'' cost allocation method, to estimate costs for the CT and MRI APCs.

2. Proposed Data Development and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the OPPS payment rates for CY 2022.

The Hospital OPPS page on the CMS website on which this proposed 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 proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later 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 2019 claims that were used to calculate the proposed payment rates for this CY 2022 OPPS/ASC proposed rule.

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. For 2022, we propose to continue to use geometric mean costs to calculate the relative weights on which the proposed CY 2022 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2022 shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier ''PN'', which indicates 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 final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2022 OPPS, we will continue to remove claim lines with modifier ''PN'' from the ratesetting process.

For details of the claims accounting process used in this proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this CY 2022 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

a. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

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.

We propose 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, to address the differences in CCRs and to better reflect hospitals' costs, we propose 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 propose to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports to simulate blood-specific CCRs for those hospitals. We propose to calculate the costs upon which the proposed CY 2022 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 continue to believe that using this methodology in CY 2022 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 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. We propose 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 proposed payment rates of the C–APCs), we propose not to 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 66795 through 66796) for

more information about our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C–APC).

We refer readers to Addendum B of this proposed rule (which is available via the internet on the CMS website) for the proposed CY 2022 payment rates for blood and blood products (which are generally 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).

For CY 2022, we propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology.

(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.

For CY 2022, except where otherwise indicated, we propose to use the costs derived from CY 2019 claims data to set the proposed CY 2022 payment rates for brachytherapy sources because CY 2019 is the year of data we propose to use to set the proposed payment rates for most other items and services that would be paid under the CY 2022 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and brachytherapy source C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm), we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also propose 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 propose 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 propose 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 2022 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the internet on the CMS website) and identified with status indicator ''U''.

For CY 2018, we assigned status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm^2. For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2018 claims data available for the final CY 2020 OPPS/ASC final rule with comment period included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm^2. In response to comments from stakeholders, we agreed with commenters that given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of 1.02 per mm^2 may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy 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 maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2020. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2021.

As discussed in Section X.E. of this CY 2022 OPPS/ASC proposed rule, given our concerns with CY 2020 data as a result of the COVID–19 PHE, in general we are proposing to use CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS. Therefore, we are proposing to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2022.

Additionally, for CY 2022 and subsequent calendar years, as discussed in Section X.C., we are proposing to establish a Low Volume APC policy for New Technology APCs, clinical APCs, and brachytherapy APCs. For these

APCs with fewer than 100 single claims that can be used for ratesetting purposes in the existing claims year, we are proposing to use up to four years of claims data to establish a payment rate for each item or service as we currently do for low volume services assigned to New Technology APCs. Further, we propose to calculate the cost for Low Volume APCs based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost. We are proposing to designate 5 brachytherapy APCs as Low Volume APCs for CY 2022. For more information on our Low Volume APC proposal, see Section X.C. of this CY 2022 OPPS/ASC proposed rule.

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 via email to *outpatientpps@cms.hhs.gov* or by mail 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 2022

(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 1 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. In the CY 2019 OPPS/ASC final rule with comment period, we created 3 new C–APCs, increasing the total number to 65 (83 FR 58844 through 58846). In the CY 2020 OPPS/ASC final rule with comment period, we created two new C–APCs, increasing the total number to 67 C–APCs (84 FR 61158 through 61166). Most recently, in the CY 2021 OPPS/ASC final rule, we created two new C–APCs, increasing the total number to 69 C–APCs (85 FR 85885).

Under our C–APC 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 proposed rule (which is available via the internet on the CMS website).

In the interim final rule with request for comments (IFC) entitled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', published on November 6, 2020, we stated that, effective for services furnished on or after the effective date of the IFC and until the end of the PHE for COVID–19, there is an exception to the OPPS C–APC policy to ensure separate payment for new COVID–19 treatments that meet certain criteria (85 FR 71158 through 71160). Under this exception, any new COVID–19 treatment that meets the following two criteria will, for the remainder of the PHE for COVID–19, always be separately paid and will not be packaged into a C–APC when it is provided on the same claim as the primary C–APC service. First, the treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID–19, as indicated in section ''I. Criteria for Issuance of Authorization'' of the FDA letter of authorization for the emergency use of the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID–19. Second, the emergency use authorization (EUA) for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by the FDA to treat COVID–19 disease and not limit its use to the inpatient setting. For further information regarding the exception to the C–APC policy for COVID–19 treatments, please refer to the November 6, 2020 IFC (85 FR 71158 through 71160).

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;''
- 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 set 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. 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, as stated in section 1833(t)(2) of the Act and section III.B.2. of this proposed 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 2022, we propose 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 list the complexity adjustments for ''J1'' and add-on code combinations for CY 2022, along with all of the other proposed complexity adjustments, in Addendum J to this CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

Addendum J to this proposed rule includes 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 this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and are 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 are 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 are proposed to be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows 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.

(2) 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. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator ''J1'', payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was 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.

To address this issue and ensure that there is sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding 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. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator ''J2'' when they are included on a claim with a ''J2'' service starting in CY 2020 (84 FR 61167). We proposed to continue 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'' or ''J2'' service assigned to a C–APC.

(3) Additional C–APCs for CY 2022

For CY 2022 and subsequent years, we propose to continue to apply the C–APC payment policy methodology. 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, we are not proposing to convert any standard APCs to C–APCs in CY 2022, thus we propose that the number of C–APCs for CY 2022 would be the same as the number for CY 2021, which is 69 C–APCs.

Table 1 lists the proposed C–APCs for CY 2022, all of which were established in past rules. All C–APCs are displayed in Addendum J to this proposed rule (which is available via the internet on the CMS website). Addendum J to this proposed rule also contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information.

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TABLE 1: Proposed CY 2022 C-APCs

C-APC	CY 2022 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	
5182	Level 2 Vascular Procedures	VASCX	
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	
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	

C-APC	CY 2022 APC Group Title	Clinical Family	New C-APC
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 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	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 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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c. Proposed 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.

(1) Mental Health Services Composite APC

We propose 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.

We propose 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 2022. In addition, we propose 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.

(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, 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 2 below.

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).

For CY 2022, we propose 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 continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

For CY 2022, except where otherwise indicated, we propose to use the costs derived from CY 2019 claims data to set the proposed CY 2022 payment rates. Therefore, for CY 2022, the payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) are based on proposed geometric mean costs calculated from CY 2019 claims available for this CY 2022 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), are identified by asterisks in Addendum N to this CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website) and are discussed in more detail in section II.A.1.b. of this CY 2022 OPPS/ASC proposed rule.

For this CY 2022 OPPS/ASC proposed rule, we were able to identify approximately 1.04 million ''single session'' claims out of an estimated 2.2 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 47 percent of all eligible claims, to calculate the proposed CY 2022 geometric mean costs for the multiple imaging composite APCs. Table 2 of this CY 2022 OPPS/ASC proposed rule lists 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 2022.

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TABLE 2: PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2022 APC 8004 (Ultrasound Composite)	**CY 2022 Approximate APC Geometric Mean Cost = $290.73**
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	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2022 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2022 Approximate APC Geometric Mean Cost = $218.46**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
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
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2022 APC 8006 (CT and CTA with Contrast Composite)	**CY 2022 Approximate APC Geometric Mean Cost = $424.02**
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
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
70487	Ct maxillofacial w/dyc
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/dyc
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
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* 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 2022 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2022 Approximate APC Geometric Mean Cost = $509.23**
0609T	Mrs disc pain acquisj data
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 dyc
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
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2022 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2022 Approximate APC Geometric Mean Cost = $821.31**
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
70549	Mr angiograph neck w/o & 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. Proposed 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 beneficiary. 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 may occur 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), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59250), the CY 2019 OPPS/ASC final rule with comment period (83 FR 58854), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 85894). 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 2022, 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 for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department 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.

For CY 2022, we propose no changes to the overall packaging policy previously discussed. We propose to continue to conditionally package the costs of selected newly identified ancillary services into payment for 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 a proposed change to an ASC payment system packaging policy for CY 2022 and solicit comment on potential additional changes to that policy and application of that policy to the OPPS.

b. Proposed Payment Policy for Non-Opioid Pain Management Drugs and Biologicals That Function as Surgical Supplies Under the ASC Payment System

(1) Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

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 who responded to the CY 2018 OPPS/ASC proposed rule expressed a variety of views on packaging under the OPPS. While several commenters were in support of maintaining packaging policies, most of the public comments ranged from requests to unpackage most items and services that are unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a particular drug or device.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52485), we reiterated our position with regard to payment for Exparel®, a non-opioid analgesic that functions as a surgical supply, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. We also stated in the CY 2018 OPPS/ASC final rule with comment period that we would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855), we explained that, in addition to stakeholder feedback regarding OPPS packaging policies, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission)[1] had 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 the scope and effectiveness of the Federal response to drug addiction and the opioid crisis and to make recommendations to the President for improving the Federal response to the crisis. The Commission's report 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. . . .'' We explained that, 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 had recently evaluated the impact of our packaging policy for drugs that function as a supply when used in a surgical

[1] *https://www.federalregister.gov/documents/2017/04/03/2017-06716/establishing-the-presidents-commission-on-combating-drug-addiction-and-the-opioid-crisis.*

procedure on the utilization of these drugs in both the hospital outpatient department and the ASC setting. We stated that, although we found increases in utilization of Exparel when it was paid under the OPPS, we noticed decreased utilization of Exparel under the ASC payment system. Accordingly, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855 through 58860), we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019, due to decreased utilization in the ASC setting. Historically, we 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 (79 FR 66875).

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271) was enacted. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered OPD services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C–APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B), which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8), as added by section 6082(b) of the SUPPORT Act, requires the Secretary to conduct a similar type of review as required for the OPPS and to make revisions to the ASC payment system in an appropriate manner, as determined by the Secretary.

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. We used currently available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products, to determine whether our packaging policies may have reduced the use of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2020. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, for CY 2020, the only drug that qualified for separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply was Exparel.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 to 85899), we continued the policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. For CY 2021, only two drug products met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting, and thus receive separate payment under the ASC payment system. These drugs are Exparel and Omidria.

(2) CY 2022 Evaluation of Payments for Opioids and Non-Opioid Alternatives for Pain Management and Comment Solicitation on Extending the Policy to the OPPS

As noted in the background above, over the past several years we have reviewed non-opioid alternatives and evaluated the impact of our packaging policies on access to these products. In our previous evaluations, we used currently available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products, to determine whether our packaging policies may have reduced the use of non-opioid alternatives. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 to 85899), we stated that we would continue to analyze the issue of access to non-opioid pain management alternatives in the HOPD and the ASC settings as part of any reviews we conduct under section 1833(t)(22)(A)(ii), with a specific focus on whether there is evidence that our current payment policies are creating access barriers for other non-opioid pain management alternatives for which there is evidence-based support that these products help to deter or avoid prescription opioid use and opioid use disorder.

For CY 2022, we conducted a subsequent review of payments for opioids and non-opioid alternatives as authorized by section 1833(t)(22)(A)(ii). We analyzed utilization patterns in both the HOPD and ASC settings for multiple non-opioid pain management drugs, including the two drugs that are receiving separate payment when furnished in the ASC setting under our current policy for CY 2021: Exparel and Omidria. The results of our CY 2022 review were similar to the results of our

reviews in previous years. Generally, utilization of non-opioid pain management drugs continued to increase year after year in the HOPD setting, where payment for these non-opioid alternatives is packaged with the payment for the associated surgical procedure. In the ASC setting, where Exparel and Omidria are separately paid, we also saw utilization increases for these two drugs. However, in the ASC setting, the rate of increase in utilization is much more substantial than in the HOPD setting. In particular, in the HOPD setting where payment for Exparel is packaged, utilization of Exparel increased from 19.7 million units in 2019 to 21.8 million units in 2020, whereas utilization of Exparel increased from 1.5 million units in 2019 to 3.3 million units in 2020 in the ASC setting, where Exparel is separately paid. We note that a number of reasons could explain this discrepancy other than our policy to pay separately for Exparel under the ASC payment system, including evolving clinical practice in the ASC setting, which could increase the number of surgeries performed in ASCs for which Exparel is an appropriate pain management drug.

We have consistently explained, including as recently as in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85894), that 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 may occur if separate payment is provided for the item. We have not found conclusive evidence to support the notion that the OPPS packaging policy, under which non-opioid drugs and biologicals are packaged when they function as a supply in a surgical procedure, has created financial incentives to use opioids instead of evidence-based non-opioid alternatives for pain management. For example, we have not observed decreased utilization of non-opioid alternatives for pain management in the HOPD setting. Therefore, for CY 2022, we are proposing to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting.

As explained earlier in this section, while packaging encourages efficiency and is a fundamental component of a prospective payment system, where there is an overriding policy objective to reduce disincentives for use of non-opioid products to the extent possible, we believe it may be appropriate to establish payment that reduces disincentives for use of non-opioid drugs and biologicals for pain management when there is evidence that use of those products reduces unnecessary opioid use. For these reasons, we are soliciting comment as to whether we should expand our current policy that only applies in the ASC setting—to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting—to the HOPD setting. We are interested in learning from stakeholders whether similar disincentives for the use of non-opioid pain management drugs and biologicals identified in the ASC setting exist in the HOPD setting. Previously, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59067), we identified several disincentives that were unique to the ASC setting compared to the HOPD setting, including the fact that ASCs tend to provide specialized care and a more limited range of services in comparison to hospital outpatient departments. Also, ASCs are paid, in aggregate, approximately 55 percent of the OPPS rate. Therefore, fluctuations in payment rates for specific services may affect these providers more acutely than hospital outpatient departments; and 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. Additionally, we are seeking comment on what evidence supports the expansion of this policy to the HOPD setting, including the clinical benefit that Medicare beneficiaries may receive from the availability of separate or modified payment for these products in the HOPD setting.

Finally, we are seeking comment on if we should treat products the same depending on the setting, ASC or HOPD. For example, we are seeking comment on whether products should have the same eligibility requirements to qualify for revised payment in the ASC and the HOPD settings. We are additionally seeking comment on how the additional comment solicitations described below, which refer to the ASC setting, could also be applied to the HOPD setting.

(3) Proposed Criteria for Eligibility for Separate Payment Under the ASC Payment System for Non-Opioid Pain Management Drugs and Biologicals That Function as Surgical Supplies

As described in section 1833(t)(22)(A)(i) of the Act, the Secretary shall conduct a review of payments for opioids and evidence-based non-opioid alternatives for pain management with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. In any future reviews the Secretary may determine appropriate to conduct under section 1833(t)(22)(A)(ii) of the Act, we believe it is important to establish the evidence-base for non-opioid alternatives for pain management when evaluating whether current payment policies result in an incentive for providers to use opioids instead of such evidence-based non-opioid alternatives for pain management. Accordingly, for CY 2022 and subsequent years, we are proposing two criteria that non-opioid pain management drugs and biologicals would be required to meet to be eligible for a payment revision under the ASC payment system in accordance with section 1833(t)(22)(C). The proposed criteria are intended to identify non-opioid pain management drugs and biologicals that function as supplies in surgical procedures for which revised payment under the ASC payment system would be appropriate.

Specifically, for CY 2022, we are proposing the following criteria that non-opioid pain management drugs and biologicals would be required to meet to be eligible for separate payment under the ASC payment system in accordance with section 1833(t)(22)(C):

Criterion 1: FDA Approval and Indication for Pain Management or Analgesia

We propose that the drug or biological product must be safe and effective, as determined by the FDA. We propose that the drug must be approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), generic drug application under an abbreviated new drug application under section 505(j), or, in the case of a biological product, be licensed under section 351 of the Public Health Service Act. We further propose that the drug or biological must also have an FDA-approved indication for pain management or analgesia. We believe FDA approval is an appropriate requirement for a drug or biological to

be eligible for this policy because the FDA reviews drugs and biologicals for safety and effectiveness, which would allow us to identify safe and effective non-opioid products to which this separate payment policy should apply. Given that the FDA has an existing and detailed review process already in place to review drugs and biologicals, we believe it would be appropriate and administratively efficient to utilize FDA approval as a requirement to ensure that the drugs and biologicals approved under this policy are generally safe and effective for beneficiaries. We believe the vast majority of drugs and biologicals on the market have undergone FDA review and approval, and we do not anticipate this criterion would prevent otherwise eligible drugs or biologicals from qualifying. In addition, section 1833(t)(22)(C) of the Act, our current policy, and our proposed policy all focus on pain management products. Specifically, section 1833(t)(22)(C) of the Act refers to reviews of opioid and evidence-based non opioid products for pain management. Therefore, we propose to require an FDA-approved indication for pain management or analgesia for a drug or biological to qualify as a pain management product. The FDA approval process would allow us to confirm that a drug or biological is, in fact, a non-opioid. Drugs and biologicals that are approved as opioids or opioid agonists, or that receive an opioid-related approval from the FDA would not be eligible for separate payment under this policy.

Criterion 2: Cost of the Product

Currently, under the OPPS, drugs that are not policy-packaged are subject to the drug 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 at $50 per administration during CYs 2005 and 2006. We set the packaging threshold for establishing separate APCs for drugs and biologicals through annual notice and comment rulemaking. (Please see section V.B.1.a. of this proposed rule for additional details on the drug packaging threshold policy). The proposed per-day drug packaging threshold for CY 2022 is $130.

As our second criterion, we are proposing that a drug or biological would only be eligible for a payment revision under the ASC payment system in accordance with section 1833(t)(22)(C) if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this rule. We believe this is an appropriate requirement because we believe that not all non-opioid alternative treatments are equally disincentivized by our packaging policies. In particular, the cost of non-opioid drugs and biologicals below the packaging threshold of $130 per day does not generally have a significant impact on the overall procedure costs, and we believe use of these drugs and biologicals is unlikely to be disincentivized by CMS packaging policies. However, when the per-day cost of the drug is above the drug packaging threshold, the cost of these drugs or biologicals generally has a significant impact on the overall procedure costs. Section 1833(t)(22)(A)(i) of the Act discusses financial incentives to use opioids instead of non-opioid alternative treatments. As such, we do not believe non-opioid pain management drugs that are lower in cost are generally disincentivized by our packaging policies, as their cost is more easily absorbed into the payment for the primary procedure in which they are used when compared to drugs and biologicals above the threshold. We are proposing to use the existing OPPS drug packaging threshold as it is familiar to stakeholders and its application to drugs and biologicals under this policy creates uniformity across the OPPS and ASC payment systems. Therefore, CMS is proposing that drugs and biologicals would be required to have a per-day cost that exceeds the drug packaging threshold that CMS sets annually through notice and comment rulemaking.

We also believe the use of this threshold as an eligibility criterion for drugs under consideration for a payment revision under this policy is appropriate, as it conforms with the broader goals of the OPPS and ASC payment systems. 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 beneficiary. 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, including the drug packaging threshold, support our strategic goal of using larger payment bundles to maximize hospitals' incentives to provide care in the most efficient manner. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. For the reasons mentioned above, we believe it to be appropriate to package drugs under consideration for this policy which fall below the OPPS drug packaging threshold.

We propose that non-opioid drugs and biologicals currently receiving transitional drug pass-through status in the OPPS would not be candidates for this policy as they are already paid separately under the OPPS and ASC payment system. Please see section V.A., Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals, of this proposed rule for additional details on transitional pass-through payments for drugs and biologicals. We propose that once transitional drug pass-through status expires, the non-opioid drug or biological may qualify for separate payment under the ASC payment system if it meets the proposed eligibility requirements.

We seek comment on whether there are any other non-opioid drug or biological products that would meet the proposed criteria if finalized.

(4) Proposed Regulation Text Changes

We propose to codify our proposed criteria for separate payment for qualifying non-opioid pain management drugs and biologicals that function as surgical supplies in the regulation text for the ASC payment system in a new § 416.174. In particular, we propose to provide in a new § 416.174(a)(1) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if they are approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), generic drug application under an abbreviated new drug application under section 505(j), or, in the case of a biological product, are licensed under section 351 of the Public Health Service Act. Section 416.174(a)(1) would also provide that the drug or biological must have an FDA-approved indication for pain management or analgesia. New § 416.174(a)(2) would require that the per-day cost of the drug or biological must exceed the OPPS drug packaging threshold set annually through notice and comment rulemaking.

We also propose to amend § 416.164(b)(6) to provide that non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 are ancillary items that are integral to a

covered surgical procedure and for which separate payment is allowed. We also propose to amend § 416.171(b)(1) to provide that the payment rate for non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 are paid an amount derived from the payment rate for the equivalent item or service under the OPPS, and if such a payment amount is unavailable, are contractor priced.

(5) Eligibility for Separate Payment in CY 2022 for Exparel, Omidria, and Other Non-Opioid Products for Pain Management

As discussed in the CY 2021 OPPS/ASC final rule with comment period, there are two products receiving separate payment in the ASC setting under our current policy to pay separately for non-opioid pain management treatments that function as surgical supplies when furnished in the ASC setting (85 FR 86171). These two products are Exparel (*HCPCS Code C9290, Injection, bupivacaine liposome, 1 mg*) and Omidria (HCPCS Code J1097, *phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*). Based on the current information available to us, as we explain below, we are proposing that both products would be eligible for separate payment in CY 2022 under our proposed policy. We have included our initial evaluation of these two products below.

(a) Eligibility for Separate Payment in CY 2022 for Exparel Under the Proposed Eligibility Criteria

We are proposing that Exparel would continue to receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for CY 2022. Based on CMS's internal review, we believe Exparel meets criterion 1. Exparel was approved by the FDA with a New Drug Application (NDA #022496) on 10/28/2011.[2] Exparel's FDA-approved indication is ''in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia (1). In adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia''.[3] No component of Exparel is opioid-based. Accordingly, we propose that Exparel meets criterion one.

As discussed in section (3) above, for criterion two we are proposing that a drug or biological would only be eligible for separate payment under this policy if its per-day cost exceeds the drug packaging threshold described in section V.B.1.a. of this rule. The proposed per day cost threshold for CY 2022 is $130. Using the methodology described at V.B.1.a., the per day cost of Exparel exceeds the $130 per day cost threshold. Therefore, we propose that Exparel meets criterion two.

Therefore, we are proposing that Exparel meets criteria one and two, and should receive separate payment under the ASC payment system for CY 2022.

(b) Eligibility for Separate Payment for Omidria in CY 2022 Under the Proposed Eligibility Criteria

We are proposing that Omidria would continue to receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for CY 2022. Based on our internal review, we believe Omidria would meet criterion one. Omidria was approved by the FDA with a New Drug Application (NDA #205388) on 5/30/2014.[4] Additionally, Omidria's FDA-approved indication is as ''an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for: Maintaining pupil size by preventing intraoperative miosis; Reducing postoperative pain''.[5] No component of Omidria is opioid-based. Therefore, we propose that Omidria would meet proposed criterion one.

Using the methodology described at V.B.1.a., the per day cost of Omidria exceeds the $130 per day cost threshold. Therefore, we propose that Omidria meets criterion two. Therefore, we are proposing that Omidria meets criteria one and two, and should receive separate payment under the ASC payment system for CY 2022.

(6) Comment Solicitation on Policy Modifications and Potential Additional Criteria for Revised Payment for Non-Opioid Pain Management Treatments

In addition to the proposed eligibility criteria above, we are also soliciting comment on potential policy modifications and additional criteria that may help further align this policy with the intent of section 1833(t)(22) of the Act. Below we discuss potential additional criteria. We note that, depending on the public comments we receive and our continued consideration of these potential criteria, we may adopt these criteria as part of our final policy and include them in the final regulation text; accordingly, we are providing substantial details, explanations, and considerations about these potential criteria. We welcome input from stakeholders on these and any additional policy modifications or criteria they believe would enhance our proposed policy. We are also soliciting comment on other barriers to access to non-opioid pain management products that may exist, and to what extent our policies under the OPPS or ASC payment system could be modified to address these barriers.

(a) Utilization of the Product

We have historically used utilization as a metric to determine whether a change in our payment policy was necessary to determine whether our policies create a disincentive to use non-opioid alternatives. For example, as previously discussed, Exparel's decreasing utilization in the ASC setting caused us to propose to pay separately for non-opioid pain management drugs that function as surgical supplies in the ASC setting. We have used currently available claims data in prior years to analyze the payment and utilization patterns associated with specific non-opioid alternatives to determine whether our packaging policies may have reduced the use of non-opioid alternatives. We believe that higher utilization may be a potential indicator that the packaged payment is not causing an access to care issue and that the payment rate for the primary procedure adequately reflects the cost of the drug or biological. We also believe decreased utilization could potentially indicate that our packaging policy is discouraging use of drug or biological and that providers are choosing less expensive treatments. We note that it is difficult to attribute product-specific changes in utilization to our packaging policies alone. Nonetheless, while we acknowledge certain limitations of utilization data, we believe analyzing utilization either on a product-specific basis or on a broader basis could be an important criterion in determining whether separate payment is warranted for a non-opioid pain management alternative.

Therefore, we are soliciting comment on whether specific evidence of reduced utilization should be part of our evaluation and determination of whether a non-opioid pain management product should qualify for modified

[2] Exparel. FDA Letter. 28 October 2011. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022496s000ltr.pdf.*

[3] Exparel. FDA Package Insert. 22 March 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022496s035lbl.pdf.*

[4] Omidria. FDA Letter. 30 May 2014. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205388Orig1s000ltr.pdf.*

[5] Omidria. FDA Package Insert. 08 December 2017. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.*

payment. This data may help to demonstrate that our packaging policies are causing an access issue for these products. Additionally, we realize that new products to the market may not have utilization data available, or reliable utilization data may be difficult to obtain for some products; therefore, we are also requesting comment on whether utilization data requirements should vary based on the newness of a product or its FDA marketing approval date.

(b) FDA Indication for Pain Management or Analgesia for the Drug or Biological Product

As previously discussed, section 1833(t)(22)(A) of the Act specifically refers to reviews of opioid and evidence-based non opioid products for pain management. We believe the majority of drugs and biologicals that would meet the requirements of our proposed policy would already have FDA approval as a pain management drug or as an analgesic. However, we acknowledge there may be other non-opioid products that would benefit from inclusion under this policy, but do not have a specific FDA-approved indication for pain management or analgesia, and would not satisfy criterion 1. Therefore, we are soliciting comment on whether we should allow certain FDA-approved drugs and biologicals to be eligible for separate payment under this policy without a specific FDA-approved indication for pain management or as an analgesic drug. In lieu of an FDA indication for pain management or analgesia, we are seeking comment on whether it would be appropriate to approve a product for inclusion under this policy if the pain-management or analgesia attributes of the drug or biological are recognized by a medical compendium. Similarly, we are seeking comment as to whether we should consider specialty society or national organization (such as a national surgery organization) recommendations of non-opioid pain management products that function as surgical supplies and reduce opioid use in the ASC setting, as evidence that a product meets criterion one, where a drug or biological does not have an FDA indication for pain management or analgesia.

(c) Peer-Reviewed Literature Requirement Comment Solicitation

We note that section 1833(t)(22)(B) requires the Secretary to focus on covered OPD services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary that generally involve treatment for pain management. We are also soliciting comment as to whether we should only adopt a payment revision to drugs and biologicals that function as surgical supplies in the ASC setting when those products have evidence in peer reviewed literature supporting that the product actually decreases opioid. We believe this may be appropriate to ensure Medicare payment policies would not financially incentivize use of opioids rather than evidence-based non-opioid alternative treatments, as required by section 1833(t)(22)(A)(iii) of the Act. Specifically, we are seeking comment as to whether the drug or biological's use in a surgical procedure as a non-opioid pain management product should be supported by peer-reviewed literature demonstrating a clinically significant decrease in opioid usage compared to the standard of care, and we are seeking comment on whether such decreases in opioid usage should be sustained decreases that continue into the post-operative period.

Additionally, we are seeking input from commenters as to what they believe the requirements for peer-reviewed literature requirements should be. For example, we are seeking stakeholder feedback as to whether peer-reviewed literature should demonstrate that use of the drug or biological results in at least one, or several, of the following: Decreased post-operative opioid use following surgery; decreased opioid misuse following surgery; or decreased opioid use disorder and dependency following surgery.

Additionally, we ask stakeholders if specific thresholds are necessary to determine whether these decreases are statistically and clinically significant and whether the decreases should simply be measured against placebo or the standard of care. We also request information on how stakeholders would define the standard of care in these circumstances. When evaluating literature, we would expect to examine the study methods, sample size, limitations, possible conflicts of interest, patient populations studied, and how the evidence supports the conclusion that the product can serve as a non-opioid pain management product and provide a clinically significant reduction in opioid use that continues into the post-operative period. However, we welcome input from stakeholders about additional aspects of these studies that they believe CMS should focus on for this potential criterion. Additionally, we would expect to use our discretion to assess whether the submitted studies meet these criteria, as well as for clinical applicability, literature integrity, and potential biases in consultation with our clinical advisors.

In order to provide stakeholders with some examples of what supporting evidence CMS may consider for this potential criterion, we believe it would be helpful for CMS to receive literature demonstrating that use of a non-opioid drug or biological results in a statistically and clinically significant decreased day supply of outpatient opioids prescribed after surgery discharge compared to the generally accepted standard of care, or a statistically and clinically significant decreased morphine milligram equivalents (MME) per opioid dose prescribed after surgery discharge compared to the generally accepted standard of care. We would consider the generally accepted standard of care to include pain management therapy a patient would receive in the absence of the non-opioid alternative, such as the use of localized analgesia and/or an opioid. As previously discussed, we would then expect the use of a non-opioid pain management drug or biological to result in a decline in opioids used compared to the pain management therapy a patient would receive in the absence of the non-opioid alternative. We would expect this decline in opioids to include a decreased number of opioids received by a patient intraoperatively, post-operatively, and most significantly at discharge. We are soliciting comment on additional examples or measures that would be beneficial for CMS to take into consideration. Additionally, we are seeking comment on whether we should require a specific objective measure for this criterion. We also seek input on how to assess whether changes are statistically and clinically significant. We request comment on whether stakeholders believe evidence of statistical significance should be sufficient, or whether stakeholders believe the literature should also demonstrate clinically significant differences between treatment groups as well.

(d) Alternative Payment Mechanisms for Non-Opioid Drugs and Biologicals

As previously discussed, for CY 2022, we are proposing to pay separately at ASP plus 6 percent for non-opioid pain management drugs and biologicals that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and meet our other proposed

criteria. Section 1833(t)(22)(A)(iii) requires the Secretary to consider the extent to which revisions payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management. Accordingly, separate payment is not the only possible revision that may be appropriate. We seek comment on additional payment mechanisms that may be appropriate aside from separate payment. For instance, we request feedback from stakeholders as to whether a single, flat add-on payment, or separate APC assignment, for products or procedures that use a product that meets eligibility criteria would be preferable to separate payment. We note that any revisions the Secretary determines appropriate under section 1833(t)(22)(C) must be applied in a budget neutral manner under section 1833(t)(9)(B). We also seek input from stakeholders on any other innovative payment mechanisms for eligible non-opioid drugs and biologicals for pain management.

(e) Non-Drug Products

We are also interested in information on any non-opioid non-drug products that function as surgical supplies commenters believe should be eligible for separate payment under this policy. Although we have not currently identified any non-opioid pain management non-drug products that are disincentivized by CMS packaging policies based on utilization data, we believe it is reasonable to assume that if disincentives exist for the use of non-opioid pain management drugs and biological products under the ASC payment system, they may also exist for non-opioid, non-drug products under the ASC payment system. If this is the case, we would like to address these disincentives given the severity, and importance of combatting, the opioid epidemic, regardless of whether the non-opioid product is a drug, biological, or non-drug product. We remain interested as to whether there are any non-opioid, non-drug products that may meet the proposed eligibility criteria and should qualify for separate or modified payment as discussed in section (d) above, in the ASC setting. Similarly, we are also seeking comment on if there are unique qualities of non-drug products that would make revised payment in the HOPD setting appropriate instead of, or in addition to, the ASC setting.

We are also soliciting comment on whether it is appropriate to require non-drug products to meet the same criteria being proposed for drugs and biologicals. Additionally, we are seeking comment from stakeholders on whether they believe it would be appropriate to create a broad category for non-drug products, or if a more limited category, such as for devices, would be appropriate. Specifically, we are seeking comment on whether there is information in the FDA approval for devices that would be an appropriate criterion to determine eligibility for separate payment, similar to how we are proposing to require FDA approval with an indication for pain management or analgesia for drugs and biologicals. We are also seeking comment on whether, if the non-drug product is a ''device'' as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, the device should have received FDA premarket approval, grant of a de novo request, 510(k) clearance or meet an exemption from premarket review. We are soliciting comment on all aspects of an extension of our current policy to include appropriate products that are not drugs or biologicals.

We are also soliciting comment as to how peer-reviewed literature and utilization claims data could be used as potential criteria for a policy that would apply to non-drug products. Additionally, should a payment revision be determined necessary, we are seeking comment on appropriate payment mechanisms for non-opioid, non-drug products, including assigning the non-drug product to its own APC to ensure that the product is paid separately or establishing an add-on adjustment for the cost of the non-drug product in addition to the payment for the APC to which the non-drug product is assigned. Additionally, we seek comment on whether it would be appropriate to subject non-drug products to a cost threshold similar to the one we are proposing to apply to drugs and biologicals.

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 2021 OPPS/ASC final rule with comment period (85 FR 85902 through 85903), we applied this policy and calculated the relative payment weights for each APC for CY 2021 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 2022, as we did for CY 2021, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2022 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 2022, as we did for CY 2021, we propose 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 2022, as we did for CY 2021, we propose 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 note that in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61365 through 61369), we discuss our policy, implemented on January 1, 2019, 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 a reduced rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. Specifically, under this 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 this policy, the savings that result from the change in payments for these clinic visits are not budget neutral. Therefore, the impact of this 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. For a full discussion of this policy, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

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 2022 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2021 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2022 unscaled relative payment weights.

For CY 2021, we multiplied the CY 2021 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2019 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 2022, we propose to apply the same process using the estimated CY 2022 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2021 estimated aggregate weight by the unscaled CY 2022 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 2022 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

We propose to compare the estimated unscaled relative payment weights in CY 2022 to the estimated total relative payment weights in CY 2021 using CY 2019 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we propose to adjust the calculated CY 2022 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2022 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4436 to ensure that the proposed CY 2022 relative payment weights are scaled to be budget neutral. The proposed CY 2022 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this 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 proposed rule) is included in the budget neutrality calculations for the CY 2022 OPPS.

B. Proposed 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. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2020 forecast of the FY 2022 market basket increase, the proposed FY 2022 IPPS market basket update was 2.5 percent.

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 FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435), the proposed MFP adjustment for FY 2022 was 0.2 percentage point.

Therefore, we propose that the MFP adjustment for the CY 2022 OPPS is 0.2 percentage point. We also propose that if more recent data become subsequently available after the publication of this proposed rule (for example, a more recent estimate of the market basket increase and/or the MFP adjustment), we will use such updated data, if appropriate, to determine the CY 2022 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 the CY 2022 OPPS/ASC final rule.

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 propose for CY 2022 an OPD fee schedule increase factor of 2.3 percent for the CY 2022 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 2.5 percent, less the proposed 0.2 percentage point MFP adjustment).

We propose that hospitals that fail to meet the Hospital OQR Program reporting requirements would be 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 XIV. of the proposed rule.

To set the OPPS conversion factor for 2022, we propose to increase the CY 2021 conversion factor of $82.797 by 2.3 percent. In accordance with section 1833(t)(9)(B) of the Act, we propose further to adjust the conversion factor for CY 2022 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We propose to calculate an overall budget neutrality factor of 1.0012 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2022 IPPS wage indexes to those payments using the FY 2021 IPPS wage indexes, as adopted on a calendar year basis for the OPPS.

For the CY 2022 OPPS, we propose to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We propose 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 this proposed rule. We propose to calculate a CY 2022 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2022 payments under section 1833(t) of the Act, including the proposed CY 2022 cancer hospital payment adjustment, to estimated CY 2022 total payments using the CY 2021 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2022 estimated payments applying the proposed CY 2022 cancer hospital payment adjustment were the same as estimated payments applying the CY 2021 final cancer hospital payment adjustment. Therefore, we propose to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C), as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255), we are applying a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we applied as stated in section II.F. of the proposed rule.

For this CY 2022 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2022 would equal approximately $1.03 billion, which represented 1.24 percent of total projected CY 2022 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.92 percent estimate of pass-through spending for CY 2021 and the 1.24 percent estimate of proposed pass-through spending for CY 2022, resulting in a proposed decrease to the conversion factor for CY 2022 of 0.32 percent.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2022. We estimate for the proposed rule that outlier payments would be 1.06 percent of total OPPS payments in CY 2021; the 1.00 percent for proposed outlier payments in CY 2022 would constitute a 0.06 percent decrease in payment in CY 2022 relative to CY 2021.

For this CY 2022 OPPS/ASC proposed rule, we also propose 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 propose to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.3 percent (that is, the proposed OPD fee schedule increase factor of 2.3 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2022 of $82.810 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.647 in the conversion factor relative to hospitals that met the requirements).

In summary, for 2022, we propose to use a reduced conversion factor of $82.810 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.647 in the conversion factor relative to hospitals that met the requirements).

For 2022, we propose to use a conversion factor of $84.457 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 2.3 percent for CY 2022, the required proposed wage index budget neutrality adjustment of approximately 1.0012, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.32 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a proposed conversion factor for CY 2022 of $84.457.

C. Proposed 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 proposed rule.

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). We propose to continue this policy for the CY 2022 OPPS. We refer readers to section II.H. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule (which is available via the internet on the CMS website), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2022 pre-reclassified wage index that we would use under the IPPS 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 (3) of our regulations. For 2022, we propose 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. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2021 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; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; and for FY 2021, 85 FR 58765.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2022 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals. In addition, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25405 through 25407), we proposed to implement section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) which reinstates the imputed floor wage index adjustment under the IPPS for hospitals in all-urban states effective for discharges on or after October 1, 2021 (FY 2022) using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act, as added by section 9831 of the American Rescue Plan Act, provides that for discharges occurring on or after October 1, 2021, the area wage index applicable under the IPPS to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. We further noted in the FY 2022 IPPS/LTCH PPS proposed rule that, given the recent enactment of section 9831 of Public Law 117–2 on March 11, 2021, there was not sufficient time available to incorporate the changes required by this statutory provision (the reinstatement of the imputed floor wage index) into the calculation of the IPPS provider wage index for the FY 2022 IPPS/LTCH PPS proposed rule, and we stated that we would include the imputed floor wage index adjustment in the calculation of the IPPS provider wage index in the FY 2022 IPPS/LTCH PPS final rule. We note that CMS posted, concurrent with the issuance of the FY 2022 IPPS/LTCH proposed rule, estimated imputed floor values by state in a separate data file on the FY 2022 IPPS Proposed Rule web page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. In addition, we stated in the FY 2022 IPPS/LTCH PPS proposed rule that, based on data available for the FY 2022 IPPS/LTCH PPS proposed rule, the following States would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2022: New Jersey, Rhode Island, Delaware, Connecticut, and Washington, DC. We refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25396 through 25417) for a detailed discussion of all proposed changes to the FY 2022 IPPS wage indexes.

Furthermore, 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 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755), 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.

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 provided detailed information on the update to the statistical areas since July 15, 2015, and were 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. For purposes of the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58863 through 58865), we adopted the updates set forth in OMB Bulletin No. 17–01,

effective January 1, 2019, beginning with the CY 2019 wage index.

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. Typically, interim OMB bulletins (those issued between decennial censuses) have only contained minor modifications to labor market delineations. However, the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the labor market areas than are typical for OMB bulletins issued between decennial censuses, including some new CBSAs, urban counties that became rural, rural counties that became urban, and some existing CBSAs that were split apart. In addition, some of these modifications had a number of downstream effects, such as reclassification changes. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. For purposes of the OPPS, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85907 through 85908), we adopted the updates set forth in OMB Bulletin No. 18–04 effective January 1, 2021, beginning with the CY 2021 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 18–04, we refer readers to the CY 2021 OPPS/ASC final rule with comment period.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the updates to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017 and July 1, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*.) In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area, one new component of an existing Combined Statistical Area and changes to New England City and Town Area (NECTA) delineations. As we stated in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25397), after reviewing OMB Bulletin No. 20–01, we determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare IPPS wage index for FY 2022. Specifically, the updates consisted of changes to NECTA delineations and the creation of a new Micropolitan Statistical Area, which was then added as a new component to an existing Micropolitan Statistical Area. The Medicare wage index does not utilize NECTA definitions, and, as most recently discussed in FY 2021 IPPS/LTCH PPS final rule (85 FR 58746), we include hospitals located in Micropolitan Statistical areas in each State's rural wage index. Therefore, consistent with our discussion in the FY 2022 IPPS/LTCH PPS proposed rule, while we propose to adopt the updates set forth in OMB Bulletin No. 20–01 consistent with our longstanding policy of adopting OMB delineation updates, we note that specific OPPS wage index updates would not be necessary for CY 2022 as a result of adopting these OMB updates. In other words, these OMB updates would not affect any hospital's geographic area for purposes of the OPPS wage index calculation for CY 2022.

For CY 2022, we would continue to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01, 17–01, and 18–04.

We note that, in connection with our adoption in FY 2021 of the updates in OMB Bulletin 18–04, we adopted a policy to place a 5 percent cap, for FY 2021, on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755) for a complete discussion of this transition. As finalized in the FY 2021 IPPS/LTCH PPS final rule, this transition is set to expire at the end of FY 2021. However, as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25397), given the unprecedented nature of the ongoing COVID–19 PHE, we sought comment in the FY 2022 IPPS/LTCH PPS proposed rule on whether it would be appropriate to continue to apply a transition for the FY 2022 IPPS wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04. For example, we stated that such an extended transition could potentially take the form of holding the FY 2022 IPPS wage index for those hospitals harmless from any reduction relative to their FY 2021 wage index. We further stated that if we were to apply a transition to the FY 2022 IPPS wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04, we also sought comment on making this transition budget neutral under the IPPS, as is our usual practice, in the same manner that the FY 2021 IPPS wage index transition was made budget neutral as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58755).

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. 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* (which, as of May 6, 2019, migrated to: *https://www.census.gov/programs-surveys/geography.html*). 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 CY 2022, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2022 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 rate for CY 2022. Therefore, any adjustments for the FY 2022 IPPS post-reclassified wage index, including, but not limited to, the imputed floor adjustment and any transition that may be applied (as discussed previously), would be reflected in the final CY 2022 OPPS wage index beginning on January 1, 2022. (We refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25396 through 25417) and the proposed FY 2022 hospital wage index files posted on the CMS website.) With regard to budget neutrality for the CY 2022 OPPS wage index, we refer readers to section II.B. of this CY 2022 OPPS/ASC proposed rule. We continue to believe that using the IPPS post-reclassified 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.

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 was paid under the IPPS, based on its geographic location and any applicable wage index adjustments. In this CY 2022 OPPS/ASC proposed rule, we propose to continue this policy for CY 2022, and are including below a brief summary of the major proposed FY 2022 IPPS wage index policies and adjustments that we propose to apply to these hospitals under the OPPS for CY 2022. We referred readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25396 through 25417) for a detailed discussion of the proposed changes to the FY 2022 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 index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2022, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore, we propose that the wage index that would apply for CY 2022 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to non-IPPS hospitals paid under the OPPS would include any transition we may finalize for the FY 2022 IPPS wage index as discussed previously.

For CMHCs, for CY 2022, we propose to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we propose that the wage index that would apply to CMHCs for CY 2022 would continue to include the rural floor adjustment and any adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to CMHCs would include any transition we may finalize for the FY 2022 IPPS wage index as discussed above. Also, we propose that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

Table 4A associated with the FY 2022 IPPS/LTCH PPS proposed rule (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2022 IPPS/LTCH PPS proposed rule (available for download via the website above) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2022. We are including the outmigration adjustment information from Table 2 associated with the FY 2022 IPPS/LTCH PPS proposed rule as Addendum L to this CY 2022 OPPS/ASC proposed rule with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this proposed rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index*. At this link, readers will find a link to the proposed FY 2022 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use 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. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes 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. We also use the statewide average default CCRs to determine payments for hospitals whose 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).

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 details on our process for calculating the statewide average CCRs, we refer readers to the CY 2022 OPPS proposed rule Claims Accounting Narrative that is posted on our website. We propose to calculate the default ratios for CY 2022 using cost report data from the same set of cost reports we originally used in the CY 2021 OPPS ratesetting, consistent with the broader proposal regarding 2022 OPPS ratesetting discussed in section X.E. of this proposed rule.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPPS CY proposed rule and final rule on the CMS website. We refer readers to our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; click on the link on the left of the page titled ''Hospital Outpatient Regulations and Notices'' and then select the relevant regulation to download the statewide CCRs and upper limit in the Downloads section of the web page.

E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2022

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, items paid at charges reduced to costs, 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 our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also 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 Public Law 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 2021. 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.

For CY 2022, we propose 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, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2021

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), the Congress added section 1833(t)(7), ''Transitional Adjustment to Limit Decline in Payment,'' to the Act, which requires the Secretary to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as ''held harmless'' and their payments are often referred to as ''hold harmless'' payments).

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 § 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. Table 3 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2021.

TABLE 3: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT-TO-COST RATIOS (PCRs), CY 2012 THROUGH CY 2021

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89

2. Proposed Policy for CY 2022

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 § 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.

We propose 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 are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) for CY 2022.

Under our established policy, to calculate the proposed CY 2022 target PCR, we would use the same extract of cost report data from HCRIS used to estimate costs for the CY 2022 OPPS which would be the most recently available hospital cost reports which, in most cases, would be from CY 2020. However, as discussed in Section II.A.1.a of this proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, we believe a target PCR based on CY 2020 claims and the most recently available cost reports may provide a less accurate estimation of cancer hospital PCRs and non-cancer hospital PCRs than the data used for the CY 2021 rulemaking cycle. Therefore, for CY 2022, we are proposing to continue to use the CY 2021 target PCR of 0.89. This proposed CY 2022 target PCR of 0.89 includes the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2022. For a description of the CY 2021 target PCR calculation, we refer readers to the CY 2021 OPPS/ASC final rule with comment period (84 FR 85912 through 85914).

Table 4 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2022, due to the cancer hospital payment adjustment policy. The actual amount of the CY 2022 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2022 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.

TABLE 4: ESTIMATED CY 2022 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 2022 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	31.3%
050660	USC Norris Cancer Hospital	9.9%
100079	Sylvester Comprehensive Cancer Center	16.5%
100271	H. Lee Moffitt Cancer Center & Research Institute	20.8%
220162	Dana-Farber Cancer Institute	34.3%
330154	Memorial Sloan-Kettering Cancer Center	38.1%
330354	Roswell Park Cancer Institute	14.0%
360242	James Cancer Hospital & Solove Research Institute	16.4%
390196	Fox Chase Cancer Center	11.2%
450076	M.D. Anderson Cancer Center	51.4%
500138	Seattle Cancer Care Alliance	46.5%

G. Proposed 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 2021, 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 $5,300 (the fixed-dollar amount threshold) (85 FR 85914 through 85916). 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 2019 OPPS payments, using CY 2019 claims available for this CY 2022 OPPS/ASC proposed rule, is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2019, 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 2022 OPPS/ASC proposed rule, we estimate that we paid approximately 0.92 percent of the total aggregated OPPS payments in outliers for CY 2019.

For this CY 2022 OPPS/ASC proposed rule, using CY 2019 claims data and CY 2021 payment rates, we estimated that the aggregate outlier payments for CY 2021 would be approximately 1.06 percent of the total CY 2021 OPPS payments. We provided estimated CY 2021 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 2022

For CY 2022, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We propose 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. We propose 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 this CY 2022 OPPS/ASC proposed rule.

To ensure that the estimated CY 2022 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we propose 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 $6,100.

We calculated the proposed fixed-dollar threshold of $6,100 using the standard methodology most recently used for CY 2021 (85 FR 85914 through 85916). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2020 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 2022 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2019 claims using the same inflation factor of 1.20469 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25718). We used an inflation factor of 1.13218 to estimate CY 2021 charges from the CY 2019 charges reported on CY 2019 claims. The methodology for determining this charge inflation factor is discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039). 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 propose to apply the same CCR inflation adjustment factor that we propose to apply for the FY 2022 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2022 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2022, we propose to apply an adjustment factor of 0.94964 to the CCRs that were in the April 2020 OPSF to trend them forward from CY 2020 to CY 2022. The methodology for calculating the proposed adjustment is discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25717 through 25719).

To model hospital outlier payments for this proposed rule, we applied the overall CCRs from the April 2021 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.94964 to approximate CY 2022 CCRs) to charges on CY 2019 claims that were adjusted (using the proposed charge inflation factor of 1.20469 to approximate CY 2022 charges). We simulated aggregated CY 2021 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 2021 OPPS payments. We estimated that a proposed fixed-dollar threshold of $6,100, 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 propose 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, we propose to continue 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 refer readers to section XIV. of this proposed rule.

H. Proposed 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 2022 OPPS/ASC proposed rule, 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 proposed rule and the relative payment weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (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 proposed rule (which is available via the internet on the CMS website) was calculated by multiplying the proposed CY 2022 scaled weight for the APC by the CY 2022 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 XIV of this proposed rule.

We demonstrate the steps used to determine the APC payments that will be made in a CY 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 note 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.

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 the proposed rule (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 0.9805 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 to receive the full CY 2022 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, for the CY 2021 OPPS wage index (85 FR 85907 through 85908), we adopted the updated OMB delineations based on OMB Bulletin No. 18–04 and related IPPS wage index adjustments finalized in the FY 2021 IPPS/LTCH PPS final rule. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2022 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We propose to continue to apply for the CY 2022 OPPS wage index any adjustments for the FY 2022 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we propose to apply for the CY 2022 OPPS, we refer readers to section II.C. of this proposed rule.

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 proposed rule (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2022 IPPS wage index, which are listed in Table 2 associated with the FY 2022 IPPS/LTCH PPS proposed rule and 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 2022 IPPS Proposed Rule Home Page'' and select ''FY 2022 Proposed 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 previously. For purposes of this

example, we are using 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 proposed CY 2022 full national unadjusted payment rate for APC 5071 is $638.48. The proposed reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $626.03. This proposed reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

The proposed FY 2022 wage index for a provider located in CBSA 35614 in New York, which includes the proposed adoption of IPPS 2022 wage index policies, is 1.3404. The labor-related portion of the proposed full national unadjusted payment is approximately $513.49 (.60 * $638.48 * 1.3404). The labor-related portion of the proposed reduced national unadjusted payment is approximately $503.48 (.60 * $626.03 * 1.3404). The nonlabor-related portion of the proposed full national unadjusted payment is approximately $255.39 (.40 * $638.48). The nonlabor-related portion of the proposed reduced national unadjusted payment is approximately $250.41 (.40 * $626.03). The sum of the labor-related and nonlabor-related portions of the proposed full national adjusted payment is approximately $768.88 ($513.49 + $255.39). The sum of the portions of the proposed reduced national adjusted payment is approximately $753.89 ($503.48 + $250.41).

I. Proposed 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 CYs 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. Proposed OPPS Copayment Policy

For CY 2022, we propose 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 propose 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, 2022 are included in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

As discussed in section XIV.E. of this proposed rule, for CY 2022, 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).

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B., ''Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests'' of this rule for additional details.

3. Proposed 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, $127.70 is approximately 20 percent of the full national unadjusted payment rate of $638.48. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (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 proposed rule. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of this proposed rule.

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 proposed rule, 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 0.9805.

The proposed unadjusted copayments for services payable under the OPPS that will be effective January 1, 2022, are shown in Addenda A and B to proposed rule (which are available via the internet on the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the CY 2022 OPD fee schedule increase factor discussed in section II.B. of proposed rule.

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. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on HOPD claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the American Medical Association (AMA), and consists of Category I, II, and III CPT codes. Level II, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. HCPCS codes are used to report surgical procedures, medical 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, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alphanumeric codes), which are used primarily to identify drugs, devices, ambulance services, durable medical equipment, orthotics, prosthetics, supplies, temporary surgical procedures, and medical 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 the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes and makes the

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 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 more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments 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 exclusively 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. In section XI. of this proposed rule (Proposed CY 2022 OPPS Payment Status and Comment Indicators), we discuss the various proposed status indicators used under the OPPS. We also provide a complete list of proposed status indicators and their definitions in Addendum D1 to this CY 2022 OPPS/ASC proposed rule.

1. April 2021 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2021 update, 26 new HCPCS codes were established and made effective on April 1, 2021. These codes and their long descriptors are listed in Table 5 below. Through the April 2021 OPPS quarterly update CR (Transmittal 10666, Change Request 12175, dated March 8, 2021), we recognized several new HCPCS codes for separate payment under the OPPS. In this CY 2022 OPPS/ASC proposed rule, we are soliciting public comments on the proposed APC and status indicator assignments for the codes listed Table 5. The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. These new codes that are effective April 1, 2021 are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B, Addendum D1, and Addendum D2 are available via the internet on the CMS website.

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TABLE 5.—NEW HCPCS CODES EFFECTIVE APRIL 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
A9592	Copper cu-64, dotatate, diagnostic, 1 millicurie	NP	G	9383
C9074*	Injection, lumasiran, 0.5 mg	NP	D	N/A
C9776	Intraoperative near-infrared fluorescence imaging of major extra-hepatic bile duct(s) (e.g., cystic duct, common bile duct and common hepatic duct) with intravenous administration of indocyanine green (icg) (list separately in addition to code for primary procedure)	NP	N	N/A
C9777	Esophageal mucosal integrity testing by electrical impedance, transoral (list separately in addition to code for primary procedure)	NP	N	N/A
G2020	Services for high intensity clinical services associated with the initial engagement and outreach of beneficiaries assigned to the sip component of the pcf model (do not bill with chronic care management codes)	NP	A	N/A
G2172	All inclusive payment for services related to highly coordinated and integrated opioid use disorder (oud) treatment services furnished for the demonstration project	NP	A	N/A
J1427	Injection, viltolarsen, 10 mg	NP	G	9386
J1554	Injection, immune globulin (asceniv), 500 mg	NP	G	9392
J7402	Mometasone furoate sinus implant, (sinuva), 10 micrograms	NP	G	9346
J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	NP	G	9384
J9349	Injection, tafasitamab-cxix, 2 mg	NP	G	9385
K1013	Enema tube, any type, replacement only, each	NP	Y	N/A
K1014	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control	NP	Y	N/A
K1015	Foot, adductus positioning device, adjustable	NP	Y	N/A

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve	NP	Y	N/A
K1017	Monthly supplies for use of device coded at K1016	NP	Y	N/A
K1018	External upper limb tremor stimulator of the peripheral nerves of the wrist	NP	Y	N/A
K1019	Monthly supplies for use of device coded at K1018	NP	Y	N/A
K1020	Non-invasive vagus nerve stimulator	NP	Y	N/A
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	NP	G	9391
0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements	NP	A	N/A
0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	NP	Q4	N/A
0244U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffinembedded tumor tissue	NP	A	N/A
0245U	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage	NP	A	N/A
0246U	Red blood cell antigen typing, DNA, genotyping of at least 16 blood groups with phenotype prediction of at least 51 red blood cell antigens	NP	A	N/A
0247U	Obstetrics (preterm birth), insulin-like growth factor–binding protein 4 (IBP4), sex hormone–binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous	NP	Q4	N/A

HCPCS code C9074, which was effective April 1, 2021, was deleted June 30, 2021 and replaced with HCPCS code J0224 (Injection, lumasiran, 0.5mg) effective July 1, 2021.

2. July 2021 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the July 2021 update, 55 new codes were established and made effective July 1, 2021. The codes and long descriptors are listed in Table 6 below. Through the July 2021 OPPS quarterly update CR (Transmittal 10825, Change Request 12316, dated June 11, 2021), we recognized several new codes for separate payment and assigned them to appropriate interim OPPS status indicators and APCs. In this CY 2022 OPPS/ASC proposed rule, we are

soliciting public comments on the proposed APC and status indicator assignments for the codes implemented on July 1, 2021, all of which are listed in Table 6. The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. These new codes that are effective July 1, 2021 are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B, Addendum D1, and Addendum D2 are available via the internet on the CMS website.

TABLE 6.—NEW HCPCS CODES EFFECTIVE JULY 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	NP	G	9409
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	NP	G	9410
C1761	Catheter, transluminal intravascular lithotripsy, coronary	NP	H	2033
C9075	Injection, casimersen, 10 mg	NP	G	9412
C9076	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	NP	G	9413
C9077	Injection, cabotegravir and rilpivirine, 2mg/3mg	NP	G	9414
C9078	Injection, trilaciclib, 1 mg	NP	G	9415
C9079	Injection, evinacumab-dgnb, 5 mg	NP	G	9416
C9080	Injection, melphalan flufenamide hydrochloride, 1 mg	NP	G	9417
C9778	Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)	NP	J1	5414
G0327	Colorectal cancer screening; blood-based biomarker	NP	A	N/A
J0224*	Injection, lumasiran, 0.5 mg	NP	G	9407
J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg	NP	K	9419
J7168	Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity	NP	K	9132
J9348	Injection, naxitamab-gqgk, 1 mg	NP	G	9408
J9353	Injection, margetuximab-cmkb, 5 mg	NP	G	9418
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	NP	G	9411
0640T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition, interpretation and report, each flap or wound	NP	M	N/A
0641T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition only, each flap or wound	NP	T	5732
0642T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of	NP	M	N/A

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
	deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); interpretation and report only, each flap or wound			
0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach	NP	E1	N/A
0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	NP	J1	5192
0645T	Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed	NP	E1	N/A
0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	NP	E1	N/A
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	NP	J1	5302
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	NP	S	5523
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	NP	N	N/A

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional	NP	Q1	5741
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	NP	T	5301
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	NP	T	5301
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	NP	T	5301
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	NP	J1	5302
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging	NP	J1	5374
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments	NP	C	N/A
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments	NP	C	N/A
0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score	NP	S	5733
0659T	Transcatheter intracoronary infusion of supersaturated oxygen in conjunction with percutaneous coronary revascularization during acute myocardial infarction, including catheter placement, imaging guidance (eg, fluoroscopy), angiography, and radiologic supervision and interpretation	NP	C	N/A
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach	NP	E1	N/A
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant	NP	E1	N/A
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	NP	S	5732

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (list separately in addition to code for primary procedure)	NP	N	N/A
0664T	Donor hysterectomy (including cold preservation); open, from cadaver donor	NP	E1	N/A
0665T	Donor hysterectomy (including cold preservation); open, from living donor	NP	E1	N/A
0666T	Donor hysterectomy (including cold preservation); laparoscopic or robotic, from living donor	NP	E1	N/A
0667T	Donor hysterectomy (including cold preservation); recipient uterus allograft transplantation from cadaver or living donor	NP	E1	N/A
0668T	Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary	NP	E1	N/A
0669T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each	NP	E1	N/A
0670T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; arterial anastomosis, each	NP	E1	N/A
0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug	NP	A	N/A
0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report	NP	Q4	N/A
0250U	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden	NP	A	N/A
0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma	NP	Q4	N/A
0252U	Fetal aneuploidy short tandem–repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy	NP	A	N/A

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 SI	Proposed CY 2022 APC
0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)	NP	A	N/A
0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplications, mosaicism, and segmental aneuploidy, per embryo tested	NP	A	N/A

*HCPCS code C9074, which was effective April 1, 2021, was deleted June 30, 2021 and replaced with HCPCS code J0224 effective July 1, 2021.

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3. October 2021 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2022 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2021 in the CY 2022 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2023 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2021 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2022, we are proposing to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to those new HCPCS codes that are effective October 1, 2021 to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2022 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

4. January 2022 HCPCS Codes

a. New Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2022 OPPS/ASC Final Rule With Comment Period

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2022 in the CY 2022 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2023 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2022, we propose to include in Addendum B to the CY 2022 OPPS/ASC final rule with comment period the new Level II HCPCS codes effective January 1, 2022 that would be incorporated in the January 2022 OPPS quarterly update CR. These codes will be released to the public through the January OPPS quarterly update CRs and via the CMS HCPCS website (for Level II HCPCS codes).

For CY 2022, we are proposing to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to the new HCPCS codes that will be effective January 1, 2022 to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2022 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This 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 proposed rule, and to avoid resorting to use of 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), to solicit public comments in the final rule, and to finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2022 OPPS update, we received the CPT codes that will be effective January 1, 2022 from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in Addendum B of this proposed rule 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 the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we note 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 are including the 5-digit placeholder codes and the long descriptors for the new and revised CY 2022 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can adequately comment on our proposed APCs and status indicator assignments. The 5-digit placeholder codes can be found in Addendum O, specifically under the column labeled ''CY 2022 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code''. The final CPT code numbers will be included in the CY 2022 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2022 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2022. Because the CPT codes listed in Addendum B appear with short descriptors only, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we are proposing to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2022 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website).

Finally, in Table 7 below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

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TABLE 7.—COMMENT TIMEFRAME FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2021	HCPCS (CPT and Level II codes)	April 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
July 2021	HCPCS (CPT and Level II codes)	July 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
October 2021	HCPCS (CPT and Level II codes)	October 1, 2021	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period
January 2022	CPT Codes	January 1, 2022	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2022	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period

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B. Proposed 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 (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric 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 proposed rule.

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. For CY 2022, we propose 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 2022 OPPS update will be discussed in the relevant specific sections throughout the CY 2022 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 for 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 this section of this proposed rule, for CY 2022, we propose 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 2022 OPPS update, we have identified the APCs with violations of the 2 times rule. Therefore, we propose changes to the procedure codes assigned to these APCs in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this CY 2022 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 propose 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 2022 included in this proposed rule are related to changes in costs of services that were observed in the CY 2019 claims data available for CY 2022 ratesetting. Addendum B to this CY 2021 OPPS/ASC proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we propose a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2021 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. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we propose to make for CY 2022, 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 2019 claims data available for this CY 2022 proposed rule, we found 23 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2022, and found that all of the 23 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2019 claims data available for this 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 similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have 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 8 of this proposed rule lists the 23 APCs for which we propose to make an exception under the 2 times rule for CY 2021 based on the criteria cited above and claims data submitted between January 1, 2019, and December 31, 2019, and processed on or before June 30, 2020, and updated CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

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TABLE 8.—PROPOSED CY 2022 APC EXCEPTIONS TO THE 2 TIMES RULE

Proposed CY 2022 APC	Proposed CY 2022 APC Title
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5101	Level 1 Strapping and Cast Application
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI 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
5593	Level 3 Nuclear Medicine and Related Services
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

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C. Proposed New Technology APCs

1. Background

In the CY 2002 OPPS 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 2021, 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 market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and 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 technologies and their clinical utility. Quite often, parties request that Medicare make higher payments 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 2022, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

2. Establishing Payment Rates for Low-Volume New Technology Services

Services that are assigned to New Technology APCs are typically new services that do not have sufficient claims history to establish an accurate payment for the services. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC. Some services that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider services with fewer than 100 claims annually to be low-volume services because there is a higher probability that the payment data for a service 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. As we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58890), we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS service code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the service for these low-volume services.

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 service to a New Technology APC allows us to gather claims data to price the service 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 determined in the CY 2019 OPPS/ASC final rule with comment period that it was appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determined the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). 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 services in the past (82 FR 59281). Although we have used this adjustment authority on a case-by-case basis in the past, we stated in the CY 2019 OPPS/ASC final rule with comment period that we believed it was appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order to mitigate the wide payment fluctuations that have occurred for new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, we stated that we believed that it was 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 defined as fewer than 100 claims annually. We adopted a policy to consider services with fewer than 100 claims annually as low-volume services because there is a higher probability that the payment data for a service 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. We explained that we were concerned that the methodology we use to estimate the cost of a service 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 low-volume service. 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 stated that we believed using the median or arithmetic mean rather than the geometric mean (which ''trims'' the costs of certain claims out) could 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 also explained that we believed 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 final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would seek public comments on which statistical methodology should be used for each low-volume service assigned to a New Technology APC. In the preamble of each annual rulemaking, we stated that we would 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 explained that we would 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 identified 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.

For CY 2022, we propose to continue to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using up to four years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC. However, we propose to utilize our equitable adjustment authority through our proposed universal low volume APC policy described in section X.C. of this proposed rule. Our proposed universal low volume APC policy is similar to our current New Technology APC low volume policy with the difference between the two policies being that the universal low volume APC policy would apply to clinical APCs and brachytherapy APCs, in addition to New Technology APCs, and would use the highest of the geometric mean, arithmetic mean, or median based on up to four years of claims data to set the payment rate for the APC. For New Technology APCs with fewer than 100 single claims at the procedure level that can be used for ratesetting, we would apply our proposed methodology for determining a low volume APC's cost, choosing the ''greatest of'' the median, arithmetic mean, or geometric mean at the procedure level, to apply to the individual services assigned to New Technology APCs and provide the final New Technology APC assignment for each procedure. We propose to end our separate New Technology APC low volume policy if we adopt the proposed universal low volume APC policy, as it also applies to New Technology APCs.

3. Procedures Assigned to New Technology APC Groups for CY 2022

As we described 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 2022, we propose to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have not obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. 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 FDA in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. For information on the utilization and payment history of the Argus® II procedure and the Argus® II device prior to CY 2020, please refer to the CY 2021 OPPS final rule (85 FR 85937 through 85938).

For CY 2020, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2015 through CY 2018. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $146,059, the arithmetic mean cost to be approximately $152,123, and the median cost to be approximately $151,267. All of the resulting estimates from using the three statistical methodologies fell within the same New Technology APC cost band ($145,001–$160,000), where the Argus® II procedure was assigned for CY 2019. Consistent with our policy stated in section III.C.2, we presented the result of each statistical methodology in the proposed rule, and we sought public comments on which method should be used to assign procedures described by CPT code 0100T to a New Technology APC. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fell within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000. Accordingly, we assigned CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2020.

For CY 2021, the number of reported claims for the Argus® II procedure continued to be very low with a substantial fluctuation in cost from year to year. The high annual variability of the cost of the Argus® II procedure continued to make it difficult to establish a consistent and stable payment rate for the procedure. As previously mentioned, in accordance with section 1833(t)(2)(B) of the Act, we are required to establish that services classified within each APC are comparable clinically and with respect to the use of resources. We identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2016 through CY 2019. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $148,148, the arithmetic mean cost to be approximately $153,682, and the median cost to be approximately $151,974. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fell within

the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000, and accordingly, we assigned the Argus II procedure to New Technology APC 1908 for CY 2021.

For 2022, we propose to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to establish the universal low volume APC policy described in section X.C. of this proposed rule. Consistent with this proposed policy, we calculated the geometric mean, arithmetic mean, and median costs using multiple years of claims data to select the appropriate payment rate for purposes of assigning the Argus® II procedure (CPT code 0100T) to a New Technology APC. We propose to use claims data from CY 2016 through CY 2019, which are the last four years of available OPPS claims data that we believe are appropriate for ratesetting, to determine the proposed payment rate for the Argus® II procedure for CY 2022. The claims data are the same 35 claims that were used to determine the payment rate for CPT code 0100T in CY 2021, and the estimates of the geometric mean ($148,148), the arithmetic mean ($153,682), and the median ($151,974) are the same as the estimates for CY 2021. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure are within the cost band for New Technology APC 1908, with the proposed payment rate being between $145,001 and $160,000. Accordingly, we propose to continue to assign the Argus® II procedure to New Technology APC 1908 for CY 2022. Please see Table 9 below for the proposed OPPS APC and status indicator for the Argus® II procedure (CPT code 0100T) for CY 2022.

TABLE 9: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR THE ARGUS® II PROCEDURE (CPT CODE 0100T) ASSIGNED TO NEW TECHNOLOGY APC

CY 2022 HCPCS Code	Long Descriptor	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC	Proposed CY 2022 OPPS Payment Rate
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy	T	1908	$152,500.50

b. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1561)

Effective January 1, 2021, CMS established HCPCS code C9770 (*Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent*) and assigned it to a New Technology APC based on the geometric mean cost of HCPCS code 67036. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 ($3001–$3500)). This procedure may be used to describe the administration of CPT code J3398 (*Injection, voretigene neparvovec-rzyl, 1 billion vector genomes*). This procedure was previously discussed in the CY 2021 OPPS/ASC Final Rule with comment period (85 FR 85939–85940).

CPT code J3398 (*Injection, voretigene neparvovec-rzyl, 1 billion vector genomes*) is a gene therapy for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®), was approved by FDA in December of 2017, and is indicated as an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[6] This therapy is administered through a subretinal injection, which stakeholders describe as an extremely delicate and sensitive surgical procedure. The FDA package insert describes one of the steps for administering Luxturna as, ''after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana.''

Stakeholders, including the manufacturer of Luxturna®, recommended HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*) for the administration of the gene therapy.[7] However, the manufacturer previously contended the administration was not accurately described by any existing codes as HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*) does not account for the administration itself.

CMS recognized the need to accurately describe the unique administration procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (*Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent*) to describe this process. We stated that we believed that this new HCPCS code accurately described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that HCPCS code 67036 represents a clinically similar procedure and process that approximates similar resource utilization that is associated with C97X1. However, we also recognized that it is not prudent for the code that describes the administration of this unique gene therapy, C97X1, to be assigned to the same C–APC to which HCPCS code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

Therefore, for CY 2021, we proposed to assign the services described by C97X1 to a New Technology APC with

[6] Luxturna. FDA Package Insert. Available: *https://www.fda.gov/media/109906/download.*

[7] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. *https://mysparkgeneration.com/pdf/Reimbursement_Guide_for_Treatment_Centers_Interactive_010418_FINAL.pdf.*

a cost band that contains the geometric mean cost for HCPCS code 67036. The placeholder code C97X1 was replaced by C9770 in the final rule. For CY 2021, we finalized our proposal to create C9770 (*Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent*), and we assigned this code to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of HCPCS code 67036. See Table 10 for the finalized descriptor and APC assignment of HCPCS code C9770 for CY 2021.

For CY 2022, we are proposing to continue our policy from CY 2021 to assign the services described by HCPCS code C9770 to a New Technology APC with a cost band that contains the geometric mean cost for HCPCS code 67036. We propose to continue to assign the services described by C9770 to a New Technology APC with a payment band based on the geometric mean cost for HCPCS code 67036 based on its geometric mean cost using CY 2019 claims data for CY 2022. Based on this data, the geometric mean cost of HCPCS code 67036 is $3,434.91. Therefore, we propose to assign C9770 to the corresponding New Technology APC payment band, APC 1561 New Technology—Level 24 ($3001–$3500) with a payment rate of $3250.50. Please see Table 10 below for the proposed OPPS APC and status indicator for HCPCS code C9770 for CY 2022.

TABLE 10: CY 2021 FINALIZED AND CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9770 ASSIGNED TO NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	Finalized CY 2021 OPPS SI	Finalized CY 2021 OPPS APC	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561	T	1561

c. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy

Effective January 1, 2019, CMS 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 (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). 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 would be between $8,001 and $8,500.

In claims data available for CY 2019 for the CY 2021 OPPS/ASC final rule with comment period, there were 4 claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we proposed for CY 2021 to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately $2,693, the arithmetic mean cost to be approximately $3,086, and the median cost to be approximately $3,708. The median was the statistical methodology that estimated the highest cost for the service and provided a reasonable estimate of the midpoint cost of the three claims that have been paid for this service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

For CY 2022, the only available claims for HCPCS code C9751 are from CY 2019. Therefore, we are proposing given the low number of claims for this procedure to utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC, consistent with our proposed universal low volume APC policy. Because we are using the same claims as we did for CY 2021, we found the same values for the geometric mean cost, arithmetic mean cost, and the median cost for CY 2022. Once again, the median was the statistical methodology that estimated the highest cost for the service and provides a reasonable estimate of the midpoint cost of the three claims that have been paid for this service. The payment rate calculated using this methodology falls again within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we propose to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501–$4,000)), with a proposed payment rate of $3,750.50 for CY 2022. Details regarding HCPCS code C9751 are included in Table 11.

TABLE 11: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9751 ASSIGNED TO NEW TECHNOLOGY APC

CY 2022 HCPCS Code	Long Descriptor	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC	Proposed CY 2022 OPPS Payment Rate
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	1562	$3,750.50

d. Fractional Flow Reserve Derived From Computed Tomography (FFRCT)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether or not patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/image procedure are packaged into the payment for the primary service. However, in CY 2018, we determined that HeartFlow should receive a separate payment because the service is performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan. We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50 based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately $1,500. We did not have Medicare claims data in CY 2019 for CPT code 0503T, and we continued to assign the service to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50.

CY 2020 was the first year for which we had Medicare claims data to calculate the cost of HCPCS code 0503T. For the CY 2020 OPPS/ASC final rule, there were 957 claims with CPT code 0503T of which 101 of the claims were single frequency claims that were used to calculate the geometric mean of the procedure. We planned to use the geometric mean to report the cost of HeartFlow. However, the number of single claims for CPT code 0503T was below the low-volume payment policy threshold for the proposed rule, and this number of single claims was only two claims above the threshold for the New Technology APC low-volume policy for the final rule. Therefore, we decided to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using the CY 2018 claims data to determine an appropriate payment rate for HeartFlow using our New Technology APC low-volume payment policy. While the number of single frequency claims was just above our threshold to use the low-volume payment policy, we still had concerns about the normal cost distribution of the claims used to calculate the payment rate for HeartFlow, and we decided the low-volume payment policy would be the best approach to address those concerns.

Our analysis found that the geometric mean cost for CPT code 0503T was $768.26, the arithmetic mean cost for CPT code 0503T was $960.12, and the median cost for CPT code 0503T was $900.28. Of the three cost methods, the highest amount was for the arithmetic mean. The arithmetic mean fell within the cost band for New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50. The arithmetic mean helped to account for some of the higher costs of CPT code 0503T identified by the developer and other stakeholders that may not have been reflected by either the median or the geometric mean.

For CY 2021, we observed a significant increase in the number of claims billed with CPT code 0503T. Specifically, using CY 2019 data, we identified 3,188 claims billed with CPT code 0503T including 465 single frequency claims. These totals are well above the threshold of 100 claims for a procedure to be evaluated using the New Technology APC low-volume policy. Therefore, we used our standard methodology rather than the low-volume methodology we previously used to determine the cost of CPT code 0503T. Our analysis found that the geometric mean for CPT code 0503T was $804.35, and the geometric mean cost for the service fell within the cost band for New Technology APC 1510 (New Technology—Level 10 ($801–$900)). However, providers and other stakeholders have noted that the FFRCT service costs $1,100 and that there are additional staff costs related to the submission of coronary CT image data for processing by HeartFlow.

We noted that HeartFlow is one of the first procedures utilizing artificial intelligence to be separately payable in the OPPS, and providers are still

learning how to accurately report their charges to Medicare when billing for artificial intelligence services (85 FR 85943). This is especially the case for allocating the cost of staff resources between the HeartFlow procedure and the coronary CT imaging services. Therefore, we decided it would be appropriate to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2021 as in CY 2020 in order to provide payment stability and equitable payment for providers as they continue to become more familiar with the proper cost reporting for HeartFlow and other artificial intelligence services. Accordingly, we assigned CPT code 0503T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50 for CY 2020, and we continued to assign CPT code 0503T to New Technology APC 1511 for CY 2021.

For CY 2022, we propose to use claims data from CY 2019 to estimate the cost of the HeartFlow service. Because we are using the same claims data as in CY 2021, these data continue to reflect that providers were learning how to accurately report their charges to Medicare when billing for artificial intelligence services. Therefore, we propose to continue to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2022 as in CY 2020 and CY 2021: New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)), with a payment rate of $950.50 for CY 2022, which is the same payment rate for the service as in CY 2020 and CY 2021. Please see Table 12 below for the proposed OPPS APC and status indicator for CPT code 0503T for CY 2022.

TABLE 12: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR CPT CODE 0503T ASSIGNED TO NEW TECHNOLOGY APC

CY 2022 HCPCS Code	Long Descriptor	Proposed CY 2022 OPPS SI	Proposed CY 2022 OPPS APC	Proposed CY 2022 OPPS Payment Rate
0503T	Noninvasive estimated coronary fractional flow reserve (ffr) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated ffr model	S	1511	$950.50

e. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. Table 13 lists the code descriptors, status indicators, and APC assignments for these CPT codes. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2,001–$2,500)) with a payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with a payment rate of $2,750.50. We did not receive any claims data for these services for CY 2021. Therefore, we continued to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2,001–$2,500)) with a payment rate of $2,250.50. Likewise, CPT codes 78432 and 78433 continued to be assigned to APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with a payment rate of $2,750.50.

For CY 2022, we propose to use CY 2019 claims data to determine the payment rates for CPT codes 78431, 78432, and 78433. Because these codes did not become active until CY 2020, there are no claims for these three services. Accordingly, we propose to continue to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2,001–$2,500)) with a payment rate of $2,250.50. Likewise, we propose that CPT codes 78432 and 78433 would continue to be assigned to APC 1523 (New Technology—Level 23 ($2,501–$3,000)) with a payment rate of $2,750.50. Table 13 lists code descriptors, status indicators, and APC assignments for these CPT codes. The proposed CY 2022 payment rates for CPT codes 78431, 78432, and 78433 can be found in Addendum B to the CY 2022 OPPS/ASC proposed rule.

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TABLE 13: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR CPT CODES 78431, 78432, AND 78433 ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2021 OPPS SI	OPPS CY 2021 APC	Proposed CY 2022 OPPS SI	Proposed OPPS CY 2022 APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	S	1523	S	1523
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	S	1523	S	1523

f. V-Wave Medical Interatrial Shunt Procedure

A randomized, double-blinded, controlled IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they have received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, for CY 2020, we created a temporary HCPCS code to describe the V-wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology—Level 38 ($10,001–$15,000)).

We stated in the CY 2021 OPPS final rule that we believe that similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (85 FR 85946). Therefore, the difference in the payment for HCPCS codes C9758 and C9760 is based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to New Technology APC 1590, which reflects the cost of having surgery

every time and receiving the interatrial shunt one-half of the time when the procedure is performed.

For CY 2022, we are using the same claims data that we did for CY 2021. Because there are no claims reporting HCPCS code C9758, we are proposing to continue to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2022.

Details about the HCPCS code and its APC assignment are shown in Table 14. The proposed CY 2022 payment rate for C9758 can be found in Addendum B to the CY 2022 OPPS/ASC proposed rule.

TABLE 14: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR BLINDED INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	Proposed 2022 OPPS SI	Proposed 2022 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590

g. Corvia Medical Interatrial Shunt Procedure

Corvia Medical is currently conducting its pivotal trial for their interatrial shunt procedure. The trial started in Quarter 1 of CY 2017 and is scheduled to continue through CY 2021.[8] On July 1, 2020, we established HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study) to facilitate the implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPPS final rule, we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure (85 FR 85947). Therefore, the difference in the payment for HCPCS codes C9760 and C9758 is based on how often the interatrial shunt is implanted when each code is billed. The Corvia Medical interatrial shunt is implanted every time HCPCS code C9760 is billed. Therefore, for CY 2021, we assigned HCPCS code C9760 to New Technology APC 1592 (New Technology—Level 41 ($25,001–$30,000)) with a payment rate of $27,500.50. We also modified the code descriptor for HCPCS code C9760 to remove the phrase ''or placebo control,'' from the descriptor. For CY 2022, we propose to use the same claims data as in CY 2021 to establish payment rates for services. Therefore, there are no claims for HCPCS code C9760, and we propose to continue to assign HCPCS code C9760 to New Technology APC 1592.

Details about the HCPCS code and its APC assignment are shown in Table 15. The proposed CY 2022 payment rate for C9760 can be found in Addendum B to the proposed rule.

[8] *https://clinicaltrials.gov/ct2/show/NCT03088033?term=NCT03088033&rank=1.*

TABLE 15: CY 2022 PROPOSED OPPS APC AND STATUS INDICATOR FOR NON-RANDOMIZED, NON-BLINDED INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	Proposed 2022 OPPS SI	Proposed 2022 OPPS APC
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (eg, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	T	1592

h. Supervised Visits for Esketamine Self-Administration (HCPCS Codes G2082 and G2083 APCs 1508 and 1511)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

A treatment session of esketamine consists of instructed nasal self-administration by the patient, followed by a period of post-administration observation of the patient under direct supervision of a health care professional. Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. This is the first FDA approval of esketamine for any use. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56 mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, Spravato is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours after receiving their Spravato dose; the prescriber and patient must both sign a Patient Enrollment Form; and the product will only be administered in a certified medical office where the health care provider can monitor the patient. Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration and includes 2 hours post-administration observation. HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology—Level 8 ($601–$700)) with a payment rate of $650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082, but involves the administration of more than 56 mg of esketamine. HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)) with a payment rate of $950.50.

For CY 2022, we are using CY 2019 claims data to determine the payment rates for HCPCS codes G2082 and G2083. Since these codes did not become active until CY 2020, there are no claims for these two services. Therefore, for CY 2022, we propose to continue to assign HCPCS code G2082 to New Technology APC 1508 (New Technology—Level 8 ($601–$700)) and to assign HCPCS code G2083 to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000)).

Details about the HCPCS codes and their APC assignments are shown in Table 16. The proposed CY 2022 payment rate for esketamine self-administration can be found in Addendum B to the proposed rule.

TABLE 16: CY 2021 PROPOSED OPPS APC AND STATUS INDICATOR FOR ESKETAMINE SELF-ADMINISTRATION HCPCS CODES ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2021 OPPS SI	OPPS CY 2021 APC	Proposed CY 2022 OPPS SI	Proposed OPPS CY 2021 APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1508	S	1508
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1511	S	1511

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D. Proposed OPPS APC-Specific Policy: Stromal Vascular Fraction (SVF) Therapy

SVF therapy is intended to treat knee osteoarthritis. To process SVF, the patient's own body fat (usually from the abdomen), is recovered, and then processed to isolate a cellular product, referred to in CPT codes as an autologous cellular implant, and then injected into the knee for pain relief. SVF therapy is currently described by CPT codes 0565T and 0566T, which were effective January 1, 2020. The long descriptors for both codes are as follows:

- 0565T: Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation.
- 0566T: Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral.

For CY 2021, CPT code 0565T is assigned to APC 5733 (Level 3 Minor Procedures) with a payment rate of $55.66, and CPT code 0566T is assigned to APC 5441 (Level 1 Nerve Injections) with a payment rate of $261.17. Based on recent information from the FDA, we found there is no current FDA-approved autologous cellular product derived from autologous body fat (referred to in CPT code 0565T and 0566T as ''autologous cellular implant'') associated with SVF therapy. In addition, review of the clinical trials.gov website indicate that SVF therapy is currently under clinical trial (ClinicalTrials.gov Identifiers: NCT04440189 and NCT02726945), and has not received CMS approval as investigational device exemption (IDE) studies. We note that IDE studies that have been approved and met CMS' standards for coverage are listed on the CMS Approved IDE Studies website, specifically, at *https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies*.

Consequently, for CY 2022, we are proposing not to pay under the OPPS for either code. Specifically, we are revising the status indicator for CPT code 0565T from ''Q1'' (conditionally packaged; separately payable) to ''E1'' to indicate that the code is not payable by Medicare. Similarly, we are revising the status indicator for CPT code 0566T from ''T'' (separately payable) to ''E1'' to indicate that the code is not payable by Medicare and deleting the APC assignment for this code.

We note that the CY 2022 proposed status indicators for CPT codes 0565T and 0566T can also be found in Addendum B to this proposed rule with comment period. In addition, we refer readers to Addendum D1 of this proposed rule with comment period for the status indicator (SI) definitions for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

IV. OPPS Payment for Devices

A. Proposed Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). 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 § 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 had 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 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).

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 current device pass-through payment policy.

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 11 device categories eligible for pass-through payment: C1823-Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads); C1824-Generator, cardiac contractility modulation (implantable); C1982-Catheter, pressure-generating, one-way valve, intermittently occlusive; C1839-Iris prosthesis; C1734-Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable); C2596-Probe, image-guided, robotic, waterjet ablation; C1748-Endoscope, single-use (that is disposable), Upper GI, imaging/illumination device (insertable); C1052-Hemostatic agent, gastrointestinal, topical, C1062-Intravertebral body fracture augmentation with implant (for example, metal, polymer); C1825-Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s); and C1761-Catheter, transluminal intravascular lithotripsy, coronary.

Below, we detail the expiration dates of pass-through payment status for each of the 11 devices currently receiving device pass-through payment.

The pass-through payment status of the device category for HCPCS code C1823 is scheduled to expire on December 31, 2021. Typically, we would propose to package the costs of the device described by C1823 into the costs related to the procedure with which the device is reported in the hospital claims data for CY 2022. The data for the CY 2022 OPPS proposed rule ratesetting for the procedure reported with C1823 would have been set using CY 2020 outpatient claims data processed through December 31, 2020, however, as described in section IV.A.3 of this proposed rule, due to the effects of the COVID–19 PHE, we are proposing to use CY 2019 claims data instead of CY 2020 claims data in establishing the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in final rule 2021 OPPS ratesetting. Therefore, we are proposing to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for C1823 for four quarters of CY 2022 to end on December 31, 2022. This would allow for CY 2021 claims data to inform CY 2023 rate setting for the procedure reported with C1823. This is the only device whose costs would typically be packaged into the related procedure in CY 2022 using CY 2020 claims data for ratesetting and is the only device to which this proposed policy would apply. A full discussion of this proposed policy is included in section IV.A.3 of this proposed rule.

The pass-through payment status of the device category for HCPCS code C1823 will end on December 31, 2021. The pass-through payment status of the device categories for HCPCS codes C1824, C1982, C1839, C1734, and C2596 is set to expire on December 31, 2022. The pass-through payment status of the device category for HCPCS code C1748 is set to expire on June 30, 2023. The pass-through payment status of the device category for HCPCS codes C1052, C1062, and C1825 is set to expire on December 31, 2023 and the pass-through payment status of the device category for HCPCS code C1761 is set to expire on June 30, 2024. Table 17 shows the expiration of transitional pass-through payments for these devices.

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Table 17: EXPIRATION OF TRANSITIONAL PASS-THROUGH PAYMENTS FOR CERTAIN DEVICES

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2021
C1824	Generator, cardiac contractility modulation (implantable	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024

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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). We note that, as discussed in section IV.A.4. of this CY 2022 OPPS/ASC proposed rule, we created an alternative pathway in the CY 2020 OPPS/ASC final rule that granted fast-track device pass-through payment under the OPPS for devices approved under the FDA Breakthrough Device Program for OPPS device pass-through payment applications received on or after January 1, 2020. We refer readers to section IV.A.4. of this CY 2022 OPPS/ASC proposed rule for a complete discussion of this pathway.

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA marketing authorization (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 marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization 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;

• 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

• 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 cost 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 cryoablation, 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 of 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).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive Food and Drug Administration (FDA) marketing authorization. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

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 2022

We received eight complete applications by the March 1, 2021 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2022 OPPS/ASC proposed rule. We received three of the applications in the third quarter of 2020, two of the applications in the fourth quarter of 2020, and three of the applications in the first quarter of 2021. One of the applications was approved for device pass-through payment during the quarterly review process: The Shockwave C² Coronary Intravascular Lithotripsy (IVL) catheter, which received fast-track approval under the alternative pathway effective July 1, 2021. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, the Shockwave C² Coronary Intravascular Lithotripsy (IVL) catheter is discussed below in section IV.2.b.1.

Applications received for the later deadlines for the remaining 2021 quarters (June 1, September 1, and December 1), if any, will be discussed

in the CY 2023 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 applications received by the March 1, 2021 deadline is included below.

1. Alternative Pathway Device Pass-Through Applications

We received two device pass-through applications by the March 2021 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization, and therefore are eligible to apply under the alternative pathway. As stated above in section IV.2.a of this proposed rule, under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but need to meet the other requirements for pass-through payment status in our regulation at § 419.66.

(1) RECELL System

AVITA Medical submitted an application for a new device category for transitional pass-through payment status for the RECELL System (RECELL) for CY 2022. According to the applicant, RECELL is used to process autologous donor tissue into a cell suspension autograft that is then immediately applied to the surgically prepared acute thermal burn wound.

The applicant stated RECELL is a stand-alone, single-use, battery-powered device used to process and apply an autologous skin cell suspension. According to the applicant, RECELL is a Category III medical device indicated for the treatment of acute partial-thickness and full-thickness/mixed depth thermal burn wounds and is not categorized as a skin substitute.

According to the applicant, the autograft procedure utilizing the RECELL system involves harvesting a small graft from the patient's healthy skin and placing it into the RECELL System for immediate processing into an autologous skin cell suspension. The applicant asserts that a significantly smaller autograft harvest is needed for procedures involving RECELL when compared to procedures involving a split-thickness skin graft (STSG) without RECELL; where typical STSG expansion ranges from 2:1 to 6:1, RECELL may expand skin by up to 80:1. The applicant adds the entire procedure takes place in the operating room, including surgically preparing the acute burn wound, harvesting the autograft, processing the skin cell suspension through a disaggregation process, and applying the cell suspension autograft to the wound with no culturing in a laboratory.

The applicant described the RECELL procedure in 27 steps: (1) The autograft site is identified; (2) the patient is anesthetized and prepared; (3) the nurse opens and transfers the sterile RECELL System to the operative field; (4) a self-test is performed; (5) the nurse prepares and dispenses the enzyme into the incubation well; (6) the buffer solution is drawn and dispensed into the buffering and rinsing well; (7) the RECELL processing unit is activated to heat the enzyme; (8) a thin epidermal autograft is harvested; (9) the harvested skin graft is placed in the enzyme; (10) the donor graft incubates for 15–20 minutes; (11) the sample is placed dermal side down in the mechanical scraping tray; (12) a scalpel is used to scrape the edges of the skin sample; (13) once ready, the donor skin is rinsed in the buffer solution; (14) the skin is returned to the mechanical scraping tray; (15) buffer is applied to the skin sample; (16) the skin sample is held in place with forceps; (17) the surgeon scrapes the epidermal cells; (18) the buffer syringe is used to rinse the disaggregated skin cells; (19) the surgeon draws up the autologous skin cell suspension from the tray into a syringe; (20) the suspension is then dispensed through the cell strainer to filter the suspension; (21) the filtered autologous skin cell suspension is drawn into a new 10 ml syringe; (22) the cell suspension autograft is prepared; (23) the burn wound is debrided; (24) the primary dressing (non-adherent, non-absorbent, small pore) is fixed or held only at the lower aspect of the burn wound; (25) the cell suspension autograft is applied by either spraying or dripping over the prepared wound bed; (26) after application, the primary dressing is immediately secured over the wound bed; and (27) absorbent and protective dressings are then applied as needed.

The applicant states the autologous skin cell suspension prepared using the RECELL System contains keratinocytes, fibroblasts and melanocytes. According to the applicant, keratinocytes are the primary cells of the epidermis that are responsible for healing; fibroblasts enable the creation of new extracellular matrix proteins; and melanocytes produce melanin to allow restoration of normal pigmentation. The applicant asserts the unique delivery system allows for broad and even distribution of the cell suspension autograft directly onto a prepared wound surface or in combination with a meshed skin graft.

According to the applicant, there is one commercially available product (Epicel) that is also used to create an autograft from the patient's skin that is then applied to treat acute thermal burns. The applicant's claims regarding the differences between the two products are summarized in the following Table 18:

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TABLE 18 – DIFFERENCES BETWEEN RECELL AND EPICEL ACCORDING TO APPLICANT

RECELL	Epicel
Indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older	Indicated for use in adult and pediatric patients who have deep dermal or full thickness burns
Used to treat acute thermal burns up to 50% total body surface area (TBSA)	Used to treat acute thermal burns with TBSA greater than or equal to 30%
Class III device approved under PMA process. Includes electromagnetic warnings to include that it should not be used in presence of flammable anesthetic.[9] Contraindicated for treatment of infected or necrotic tissue, in those hypersensitive to trypsin or sodium lactate solution.[10]	Approved under a Humanitarian Device Exception (HDE). HDE devices are exempt from the effectiveness requirements for PMAs.[11] Includes a black box warning noting a serious risk of squamous cell carcinoma.[12] Contraindicated in those with history of hypersensitivity following exposure to vancomycin, amikacin, or amphotericin or those with sensitivities to bovine or murine materials.[13]
Requires a single operative session to treat the patient.	Surgical procedures separated by a period of two or more weeks are required for harvesting and placement of cultured tissue sheets. Multiple operative sessions may also be required for cultured tissue sheet placements.
Cell suspension autograft prepared in the operating room and immediately applied	Harvested autograft cultured in an off-site laboratory, taking approximately 17 days to culture for application at a later date[14]
No blood samples needed	Blood samples must be taken and archived on the date of the procedure per FDA protocol

With respect to the newness criterion at § 419.66(b)(1), RECELL received FDA Breakthrough Designation effective January 1, 2020. The applicant states that RECELL received premarket approval (PMA) on September 20, 2018. The applicant adds that RECELL is a Class III medical device indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. We received the application for a new device category for transitional pass-through payment status for RECELL on August 7, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the RECELL meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, RECELL is integral to the service provided, 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. The applicant also claimed that RECELL 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. However, given the applicant's description of RECELL as a device that processes tissue into an autograft, it appears that the RECELL system may

[9] Instructions for use—RECELL® Autologous Cell Harvesting Device. Food and Drug Administration. *https://www.fda.gov/media/116382/download.*

[10] Ibid.

[11] Humanitarian Device Exemption (HDE) Program—Guidance for Industry and FDA Staff. U.S. Department of Health and Human Services. Food and Drug Administration. Issued September 6, 2019. Accessed on March 30, 2021 and available at: *https://www.fda.gov/media/74307/download.*

[12] Manufacturer Important Drug Warning: Serious Risk with Use of Epicel (cultured epidermal autografts): Squamous Cell Carcinoma (SCC). June 2014. Food and Drug Administration. Accessed on March 30, 2021 and available at: *https://www.fda.gov/media/102746/download.*

[13] Directions for Use—Epicel (cultured epidermal autografts). Food and Drug Administration. *https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/epicel-cultured-epidermal-autografts.*

[14] Epicel Surgical Guidelines. Epicel website. Accessed on March 30, 2021 and available at: *https://www.epicel.com/pdfs/Epicel%20SurgicalGuide%202018%20DIGITAL.pdf.*

not be surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion. We believe the product of the RECELL system, the suspension, may be applied on a wound, but we are not certain that this suspension qualifies as a device. We are inviting public comments on whether RECELL meets the eligibility criteria at § 419.66(b).

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 yet identified an existing pass-through payment category that describes RECELL. We are inviting public comment on whether RECELL meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization in the CY 2020 OPPS/ASC final rule (84 FR 61295). The RECELL System has a Breakthrough Device designation and marketing authorization from the FDA and therefore is not evaluated for substantial clinical improvement. We note that the applicant has applied for the New Technology Add-on Payment under the Alternative Pathway for Breakthrough devices in the FY 2022 IPPS/LTCH proposed rule (86 FR 25385 through 25388).

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 RECELL would be reported with the HCPCS codes listed in the following Table 19:

TABLE 19 – HCPCS CODES REPORTED WITH RECELL

HCPCS Code	Short Descriptor	SI	APC
Epidermal Autograft Procedures			
15110	Epidrm autogrft trnk/arm/leg	T	5054
15111	Epidrm autogrft t/a/l add-on	N	
15115	Epidrm a-grft face/nck/hf/g	T	5054
15116	Epidrm a-grft f/n/hf/g addl	N	
Split-Thickness Skin Graft Procedures			
15100	Skin splt grft trnk/arm/leg	T	5054
15101	Skin splt grft t/a/l add-on	N	
15120	Skn splt a-grft fac/nck/hf/g	T	5055
15121	Skn splt a-grft f/n/hf/g add	N	
Surgical Preparation Procedures			
15002	Wound prep trk/arm/leg	T	5054
15003	Wound prep addl 100 cm	N	
15004	Wound prep f/n/hf/g	T	5053
15005	Wnd prep f/n/hf/g addl cm	N	

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To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5054—Level 4 Skin Procedures, which had a CY 2020 payment rate of $1,622.74 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). HCPCS code 15110 had a device offset amount of $13.47 at the time the application was received. According to the applicant, the cost of the RECELL is $7,500.

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 $7,500 for RECELL is 462 percent of the applicable APC payment amount for the service related to the category of devices of $1,622.74 ((7,500/1,622.74) × 100 = 462.2 percent). Therefore, we believe RECELL meets the first cost significance requirement.

The second cost significance requirement, 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 $7,500 for RECELL is 55,679 percent of the cost of the device-related portion of the APC payment amount for the related service of $13.47 (($7,500/$13.47) × 100 = 55,679.3 percent). Therefore, we believe that RECELL meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $7,500 for RECELL and the portion of the APC payment amount for the device of $13.47 is 461 percent of the APC payment amount for the related service of $1,622.74 ((($7,500 − $13.47)/$1,622.74) × 100 = 461.4 percent). Therefore, we believe that RECELL meets the third cost significance requirement.

We are inviting public comment on whether the RECELL meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) Shockwave C² Coronary Intravascular Lithotripsy (IVL) Catheter

Shockwave Medical submitted an application for a new device category for transitional pass-through payment status for the Shockwave C² Coronary Intravascular Lithotripsy (IVL) catheter (Coronary IVL) for CY 2022. The applicant asserts the Coronary IVL catheter is a proprietary lithotripsy device delivered through the coronary arterial system of the heart to the site of an otherwise difficult to treat calcified stenosis, including calcified stenosis that is anticipated to exhibit resistance to full balloon dilation or subsequent uniform coronary stent expansion. According to the applicant, energizing the lithotripsy device generates intermittent sound waves within the target treatment site, disrupting calcium within the lesion and allowing subsequent dilation of a coronary artery stenosis using low balloon pressure. According to the applicant, the Coronary IVL System is comprised of the following components:

(1) IVL Generator—a portable, rechargeable power source that is capital equipment and reusable.

(2) IVL Connect Cable—a reusable cable used to connect the IVL Generator to the IVL Catheter.

(3) Coronary IVL Catheter—a sterile, single-use catheter that delivers intravascular lithotripsy within the target coronary lesion.

According to the applicant, during a percutaneous coronary intervention (PCI) procedure, the physician determines that a lesion has severe calcification. The applicant states the Coronary IVL catheter is introduced into the lesion where lithotripsy is delivered to crack the calcification to facilitate the optimal dilatation of the vessel and placement of a coronary stent. The applicant adds that the catheter is removed, and the physician then implants a coronary stent to treat the lesion.

The applicant asserts that Coronary IVL is different from other devices used during PCI procedures as it delivers localized lithotripsy to crack the calcified lesion prior to the placement of a coronary stent. According to the applicant there are other devices that may be utilized to remove calcium within the vessel (that is, atherectomy), however, these devices utilize some form of cutting or laser to remove or ablate the calcium and can only address the calcium nearest to the vessel lumen. According to the applicant, Coronary IVL addresses the calcium within the lumen as well as within the vessel walls.

According to the applicant, Coronary IVL is used to treat a subset of patients identified for a PCI procedure to treat their coronary artery disease where approximately 15 percent of lesions in patients being eligible for a PCI procedure have severe calcification. The applicant adds the Shockwave C² Coronary IVL catheter is utilized during PCI procedures and does not replace any devices currently utilized to complete the procedure (for example, guidewires, angioplasty balloons, stent(s), vascular closure, etc.) that are packaged into the APC payment rate. According to the applicant, based on the FDA labeling for the Coronary IVL catheter, it will be utilized prior to the placement of a coronary stent.

With respect to the newness criterion at § 419.66(b)(1), the Coronary IVL received FDA premarket approval (PMA) for the Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C² Coronary Intravascular Lithotripsy (IVL) Catheter on February 12, 2021 and is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting. The Coronary IVL received FDA Breakthrough Device designation on August 19, 2019, and is indicated for lithotripsy-enabled, low-pressure dilatation of calcified, stenotic de novo coronary arteries prior to stenting. We received the application for a new device category for transitional pass-through payment status for the Coronary IVL on February 26, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comment on whether the Coronary IVL meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Coronary IVL is integral to the service provided, is used for one patient only, comes in contact with human tissue and is surgically inserted in a patient until the procedure is completed. The applicant also claimed that Coronary IVL 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. We are inviting public comments on whether Coronary IVL meets the eligibility criteria at § 419.66(b).

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. The applicant identified five established categories which they believe are not appropriate representatives of the Coronary IVL: (1) C1714 and C 1724 include devices that use mechanical cutting tools, (2) C1725 includes balloon angioplasty, (3) C1885 which uses laser, beams of light to break up vessel obstructions, and (4) C2623 which includes a drug coated balloon. We have not identified an existing pass-through payment category that describes Coronary IVL and we are inviting public comment on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization in the CY 2020 OPPS/ASC final rule (84 FR 61295). Coronary IVL has a Breakthrough Device designation and marketing authorization from the FDA and therefore is not evaluated for substantial clinical improvement. We note that the applicant has applied for the New Technology Add-on Payment under the Alternative Pathway for Breakthrough devices in the FY 2022 IPPS/LTCH proposed rule (86 FR 25388 through 25389).

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 Coronary IVL would be reported with the HCPCS codes listed in the following Table 20:

TABLE 20 – HCPCS CODES REPORTED WITH CORONARY IVL

HCPCS Code	Short Descriptor	SI	APC
92928	Prq card stent w/angio 1 vsl	J1	5193
92929	Prq card stent w/angio addl	N	
92933	Prq card stent/ath/angio	J1	5194
92934	Prq card stent/ath/angio	N	
92941	Prq card revasc mi 1 vsl	C	
92943	Prq card revasc chronic 1vsl	J1	5193
92944	Prq card revasc chronic addl	N	
C9600	Perc drug-el cor stent sing	J1	5193
C9601	Perc drug-el cor stent bran	N	
C9602	Perc d-e cor stent ather s	J1	5194
C9603	Perc d-e cor stent ather br	N	
C9606	Perc d-e cor revasc w ami s	C	
C9607	Perc d-e cor revasc chro sin	J1	5194
C9608	Perc d-e cor revasc chro add	N	

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5193—Level 3 Endovascular Procedures, which had a CY 2021 payment rate of $10,042.94 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). HCPCS code 92928 had a device offset amount of $3,607.42 at the time the application was received.

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 for Coronary IVL of $5,640 is 56 percent of the applicable APC payment amount for the service related to the category of devices of $10,042.94 (($5,640/10,042.94) × 100 = 56 percent). Therefore, we believe Coronary IVL meets the first cost significance requirement.

The second cost significance requirement, 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 for Coronary IVL of $5,640 is 156 percent of the cost of the device-related portion of the APC payment amount for the related service of $3,607.42 (($5,640/$3,607.42) × 100 = 156 percent). Therefore, we believe that Coronary IVL meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $5,640 for Coronary IVL and the portion of the APC payment amount for the device of $3,607.42 is 20 percent of the APC payment amount for the related service of $10,042.94 (($5,640 − $3,607.42)/$10,042.94) × 100= 20 percent. Therefore, we believe that Coronary IVL meets the third cost significance requirement.

We are inviting public comment on whether the Coronary IVL meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

As specified above, the Coronary IVL application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2021. We are inviting public comment on whether the Coronary IVL should continue to receive transitional pass-through payment under the alternative pathway for devices that are FDA market authorized and that have an FDA Breakthrough Device designation.

2. Traditional Device Pass-Through Applications

(1) AngelMed Guardian® System

Angel Medical Systems submitted an application for a new device category for transitional pass-through payment status for the AngelMed Guardian® System (Guardian®) for CY 2022. The applicant asserted that the Guardian® is a proactive diagnostic technology that monitors a patient's heart's electrical activity for changes that may indicate an Acute Coronary Syndrome (ACS) event (that is, STEMI, NSTEMI, or unstable angina) related to blockage of a coronary artery which prevents the heart muscle from receiving sufficient oxygen. The Guardian® is a device implanted in the upper left chest and connects to an active fixation intracardiac lead attached to the apex of the right ventricle. The applicant asserts the Guardian® consists of an implantable medical device (IMD) which is composed of the header with an antenna for communication and the can with circuitry, radio, vibratory motor, and battery. According to the applicant, the Guardian® system also includes an external device that communicates with the IMD and provides redundant patient notification using auditory and visual alarms. Lastly, the applicant states the Guardian® system includes a physician programmer, a capital device, used to program the IMD and download cardiac data captured by the IMD.

According to the applicant, the Guardian® system relies upon the gold standard of changes to the ST-segment of a patient's heartbeat to diagnose a heart attack. According to the applicant, the Guardian® system uses an intracardiac lead to sense cardiac data and proprietary machine learning algorithms to assess acute changes to the ST-segment on a continuous, real-time basis. The applicant asserts these changes are compared to a patient's normal baseline reference that is computed over the prior twenty-four hours of monitored heart activity. According to the applicant, if the Guardian® detects a statistically abnormal acute change relative to this baseline, it notifies the patient to the potential ACS event by providing an alarm: The implanted device will vibrate, and the external device will flash and beep. According to the applicant, patients are instructed to seek urgent medical assistance when the system activates, even in the absence of ACS symptoms.

According to the applicant, the Guardian® system implantation will typically be an outpatient procedure and, following 10–14 days, is programmed in the physician office. The applicant asserts the patient undergoes training on the Guardian® and has follow-up visits every six months to review the device data. The applicant states that the emergency alarm is intended to be used as an adjunct to symptoms; in the absence of an emergency alarm patients are instructed not to ignore symptoms of an ACS event. The applicant asserts that while current technologies detect and provide therapy for cardiac medical conditions related to abnormal heart rate and rhythm, the AngelMed Guardian® system is the only FDA approved technology for providing detection and patient notification of ACS events so that patients more reliably and urgently seek medical care.

With respect to the newness criterion at § 419.66(b)(1), the AngelMed Guardian® system first received FDA 510(k) clearance on April 9, 2018 under premarket approval (PMA) number P150009. The manufacturers received a Category B Investigational Device Exemption (IDE) as of January 27, 2020 for the use of the device in their continued access study, AngelMed for Early Recognition and Treatment of STEMI (ALERTS). According to the applicant, the device is anticipated for U.S. market availability in quarter three of 2021. We received the application for a new device category for transitional pass-through payment status for the Guardian® system on February 28, 2021, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comment on whether the Guardian® system meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Guardian® is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted temporarily. The applicant also claimed that Guardian® 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. We are inviting public comments on whether Guardian® meets the eligibility criteria at § 419.66(b).

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 yet identified an existing pass-through payment category that describes Guardian®. We are inviting public comment on whether Guardian® meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization.

The applicant stated that Guardian® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant asserted that Guardian® offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than is currently possible and this earlier diagnosis results in better outcomes.[15] In support of this claim the applicant submitted two published articles, the first by Gibson et al. and the second by Holmes et al.[16] [17]

[15] 66 FR 55852, November 2, 2001.

[16] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[17] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients with Acute Coronary Syndrome Events. JACC, 74(16), 2047–2055.

The first study is a randomized control trial with 907 subjects who were implanted with the Guardian® system and randomized 1:1 to either active or deactivated alarms.[18] According to the authors, all subjects received education regarding the importance of minimizing symptom-to-door time in the presence of chest pain or ischemic equivalents, regardless of alarm status. The authors state that patients were not blinded to their randomization status. After randomization patients returned for follow-up visits at 1, 3, 6, and every six months thereafter. In all patients, the Guardian® system captured electrogram data up to 24 hours before and 8 hours after a triggered alarm for later review. According to the authors, the primary safety endpoint was the absence of system-related complications that required a system revision or invasive intervention to resolve in at least 90 percent of subjects through six months. The primary efficacy endpoint was a composite of: (1) Cardiac or unexplained death; (2) new Q-wave MI; and (3) detection-to-presentation time >2 h for a documented coronary occlusion event. Electrocardiogram (ECG) tracings were obtained prior to implantation, at randomization, at 1, 3, and 6 months, and at every emergency presentation to evaluate for a Q-wave MI not present at baseline. An exploratory dual baseline ECG analysis was performed, according to the authors, because Q-waves may be transient between implantation and randomization. The dual baseline ECG analysis evaluates for the presence of new Q waves across subsequent ECGs. At the start of the trial, 456 patients were identified as controls and 451 as treated; at six months, 446 controls remained and 437 treated remained. The authors stated that subject enrollment ceased after 900 subjects were randomized and therefore an alpha penalty of 0.25 was taken for the interim look at event rates after 600 subjects.

According to the authors, the control and treatment groups were well matched at baseline.[19] The primary safety endpoint was met with 96.7 percent freedom (posterior probability >0.999) with a total of 31 system-related complications in 30 (3.3 percent) subjects with infections being the predominant cause of complications. The authors stated that ACS events occurrence was low. At 7, 30, 50, 70, and 90 days there were no statistical differences between the control and treated groups on the primary composite efficacy endpoint. At each time interval, the treated group had lower rates of the primary endpoint than the control group. Statistical differences were observed between treated and control groups in the dual baseline ECG exploratory analysis particularly at 50, 70, and 90 days after a confirmed occlusive event favoring the treated group. At the pre-specified 7-day look back window, the median time from Guardian® notification to arrival at a medical facility was 51 minutes for the treated subjects as compared to 30.6 hours for control subjects (Pr [pt < pc] >0.999). Subject arrival within 2 hours of a detected and confirmed coronary occlusion occurred in 85 percent (29 of 34) of the treatment group compared with only 5 percent of the control group, with the majority of patients in the control arm presenting after 7 days. However, the authors asserted that despite a numerical reduction in new Q-wave MI using single and dual baseline ECGs at any of the pre-specified look-back windows, the posterior probability of superiority did not reach statistical significance. The applicant added that 22 percent (42/193) of the confirmed ACS events were detected due to Emergency Department (ED) visits prompted by alarms in the absence of symptoms; that silent MIs typically account for approximately 30 percent of all MIs and are historically associated with increased rates of morbidity and mortality.[20]

The second article expanded on the previously discussed study with a post hoc analysis of two coprimary efficacy endpoints: Superiority of positive predictive value (PPV) and noninferiority of false positive rate for ED visits prompted by alarms compared to symptoms-only.[21] According to the authors, these primary endpoints were assessed by comparing ED visits for an Alarms OFF group (control subjects during the randomized 6-month period) to those of an Alarms ON group (including both the treatment subjects during the first 6 months and all implanted patients beyond 6 months with alarms activated). The authors stated the expanded analysis adjudicated ED visits into either true or false-positive ACS events based on independent review of cardiac test data. The authors stated that the annual rate for Clinical Events Committee (CEC)—adjudicated ACS events was 0.151 (33 of 218.15) in the Alarms OFF group and 0.124 (193 of 1,557.64) in the Alarms ON group. In the Alarms OFF group, of the 181 ED visits, the CEC adjudicated 33 (18 percent) as ACS events (MI = 22 [67 percent]; unstable angina (UA) ¼ 11 [33 percent]), with the remaining visits adjudicated as due to either stable CAD or indeterminate etiology. The median symptom-to-door time for Alarms OFF ACS events was 8.0 h (95 percent confidence interval [CI]: 3.2 to 47.5 h). In Alarms ON subjects, of the 970 ED visits, the CEC adjudicated 193 (20 percent) as ACS events, with the remainder classified as stable CAD, indeterminate events, and/or a false-positive alarm. Of the 193 ACS events, 89 events (46 percent) were prompted by alarms (with or without symptoms; MI ¼ 40 [45 percent]; UA ¼ 49 [55 percent]). The remaining 104 visits (54 percent) were prompted by symptoms only (MI ¼ 60 [58 percent]; UA ¼ 44 [42 percent]). An overall median arrival time of 1.7 h was found for the Alarms ON group composite including all 3 prompt types for ED arrival (alarms only, alarms þ symptoms, or symptoms only), which was significantly shorter than the 8.0 h delay of the Alarms OFF group (p < 0.0001). The applicant asserts that the Guardian® system allows patients with asymptomatic ACS events to respond to the ED faster with a median pre-hospital delay of 1.4 hours.

The applicant further asserts that the Guardian® system offers more rapid beneficial resolution of the disease process treated because of the use of the device. According to the applicant, the Guardian® system increases the likelihood that a patient will correctly seek medical care for an ACS event in a timely manner that reduces pre-hospital delay and associated risk of heart damage (for example, larger infarct size, ejection fraction decrement)[22 23 24]

[18] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[19] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[20] Gibson, C. M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[21] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients with Acute Coronary Syndrome Events. JACC, 74(16), 2047–2055.

[22] Weaver WD, Cerqueira M, Hallstrom AP, et al. Prehospital-Initiated vs Hospital-Initiated Thrombolytic Therapy: The Myocardial Infarction

and associated downstream sequelae. More specifically, the applicant asserts that based on the results of the second discussed study, the Guardian® system Alarms ON group showed reduced pre-hospital delays, with 55 percent (95 percent confidence interval [CI]: 46 percent to 63 percent) of Emergency department visits for ACS events <2 hours compared with 10 percent (95 percent CI: 2 percent to 27 percent) in the Alarms OFF group ($p < 0.0001$).[25] The applicant adds that results were similar when restricted to myocardial infarction (MI) events.[26] The applicant states the median pre-hospital delay for MI was 12.7 hours for Alarms OFF compared to 1.6 hours in Alarms ON subjects ($p < 0.0089$) as reported in Holmes et al. (2019).[27] The applicant asserts that it is clinically recognized, due to numerous lines of evidence, that shorter total ischemia time is associated with better outcomes for ACS events.[28 29 30 31] The applicant asserts that prompt responsiveness to symptoms and decreased pre-hospital delay is a universally understood benefit which improves the health outcomes of ACS events. According to the applicant, the American Heart Association (Mission Lifeline), American College of Cardiology (Door to Balloon (D2B) Alliance), Society for Angiographic Intervention (Seconds Count™ program) and the National Heart, Lung, and Blood Institute have organized task forces and launched national programs with the goal of improving patient awareness and response to symptoms which are indicative of potential ACS events and reducing total ischemia time (that is, prehospital delay and in-hospital delay) to improve outcomes.

The applicant next asserts the device offers more rapid beneficial resolution of the disease process because the use of the Guardian® system, as compared to the standard of care relying on symptoms alone, being in the Alarm ON group was associated with a reduction in the rate of new onset of left ventricular dysfunction.[32]

Lastly the applicant asserts the use of the Guardian® system will decrease the number of future hospitalizations or physician visits. According to the applicant, the Guardian® system reduces the annual false positive rate (FPR) of Emergency Department visits (that is, spurious ED visits where no ACS is found) by 26 percent.[33] The applicant states that the FPR for all alarms on emergency visits was 0.499 per patient-year compared to 0.678 for alarms off ($p <0.001$).[34]

Based on the evidence submitted with the application, we have the following observations. Much of the claims for substantial clinical improvement are derived from two primary studies identified by the applicant and discussed above.[35 36] We note that the first study (Gibson et al. 2019) did not demonstrate statistically significant superiority of the intervention during the pre-determined study window. The authors noted a lower than expected frequency of events and the study was terminated early, two factors which may have affected these results. The results from the second study are based entirely on a post hoc analysis of data from the first article. We note that the findings presented are valuable but we seek comment on whether a post hoc analysis provides sufficient evidence to support the claim of substantial clinical improvement. Furthermore, we note that the primary efficacy endpoint was a composite of three outcomes. We are not certain that this endpoint is an appropriate measure with which to evaluate substantial clinical improvement among patients experiencing ACS events. We invite public comments on whether the Guardian® system meets 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. The applicant stated that Guardian® would be reported with the HCPCS codes listed in the following Table 21:

Triage and Intervention Trial. JAMA. 1993;270(10):1211–1216.

[23] Hasche ET, Fernandes C, Freedman SB, Jeremy RW. Relation between ischemia time, infarct size, and left ventricular function in humans. Circulation. 1995;92:710–719.

[24] Liem AL, van 't Hof AW, Hoorntje JC, de Boer MJ, Suryapranata H, Zijlstra F. Influence of treatment delay on infarct size and clinical outcome in patients with acute myocardial infarction treated with primary angioplasty. J Am Coll Cardiol. 1998;32:629–633.

[25] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[26] Holmes, D.R., Jr, Krucoff, M. W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[27] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M. S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[28] Guerchicoff A, Brener SJ, Maehara A, et al. Impact of delay to reperfusion on reperfusion success, infarct size, and clinical outcomes in patients with ST-segment elevation myocardial infarction: the INFUSE–AMI Trial (INFUSE-Anterior Myocardial Infarction). JACC Cardiovasc Interv. 2014;7(7):733–740.

[29] Flynn A, Moscucci M, Share D, et al. Trends in door-to-balloon time and mortality in patients with ST elevation myocardial infarction undergoing primary percutaneous coronary intervention. Arch Intern Med. 2010;170(20):1842–1849.

[30] De Luca G, Suryapranata H, Zijlstra F, et al. Symptom-onset-to-balloon time and mortality in patients with acute myocardial infarction treated by primary angioplasty. J Am Coll Cardiol. 2003;42(6):991–997.

[31] Gersh BJ, Stone GW. Pharmacological facilitation of coronary intervention in ST-segment elevation myocardial infarction: Time is of the essence. JACC Cardiovasc Interv. 2010;3(12):1292–1294.

[32] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

[33] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[34] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[35] Gibson, C.M., Holmes, D., Mikdadi, G., Presser, D., Wohns, D., Yee, M.K., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., & Krucoff, M.W. (2019). Implantable Cardiac Alert System for Early Recognition of ST-Segment Elevation Myocardial Infarction. Journal of the American College of Cardiology, 73(15), 1919–1927.

[36] Holmes, D.R., Jr, Krucoff, M.W., Mullin, C., Mikdadi, G., Presser, D., Wohns, D., Kaplan, A., Ciuffo, A., Eberly, A.L., 3rd, Iteld, B., Fischell, D.R., Fischell, T., Keenan, D., John, M.S., & Gibson, C.M. (2019). Implanted Monitor Alerting to Reduce Treatment Delay in Patients With Acute Coronary Syndrome Events. Journal of the American College of Cardiology, 74(16), 2047–2055.

TABLE 21 – HCPCS CODES REPORTED WITH GUARDIAN®

HCPCS Code	Short Descriptor	SI	APC
0525T	Insj/rplcmt compl iims	J1	5223
0526T	Insj/rplcmt iims eltrd only	J1	5222
0527T	Insj/rplcmt iims implt mntr	J1	5222
0528T	Prgrmg dev eval iims ip	Q1	5741
0529T	Interrog dev eval iims ip	Q1	5741
0530T	Removal complete iims-	Q1	5222
0531T	Removal iims electrode only	Q1	5221
0532T	Removal iims implt mntr only	Q1	5221

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5222—Level 2 Pacemaker and Similar Procedures, which had a CY 2021 payment rate of $8,152.58 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). HCPCS code 0527T was assigned to APC 5222 and had a device offset amount of $1,598.72 at the time the application was received.

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 for Guardian is 126 percent of the applicable APC payment amount for the service related to the category of devices of $8,152.58. Therefore, we believe Guardian® meets the first cost significance requirement.

The second cost significance requirement, 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 for Guardian® is 641 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,598.72. Therefore, we believe that Guardian® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 for Guardian® and the portion of the APC payment amount for the device of $1,598.72 is 106 percent of the APC payment amount for the related service of $8,152.58. Therefore, we believe that Guardian® meets the third cost significance requirement. We are inviting public comment on whether the Guardian® meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) BONEBRIDGE Bone Conduction Implant System

MED–EL Corporation submitted an application for a new device category for transitional pass-through payment status for the BONEBRIDGE Bone Conduction Implant System (hereinafter referred to as the BONEBRIDGE) by the March 2021 quarterly deadline for CY 2022. The BONEBRIDGE is a transcutaneous, active auditory osseointegrated device that replaces the function of the damaged outer or middle ear and can help people for whom hearing aids are ineffective or not recommended. According to the applicant, the device consists of a bone conduction implant and electronics components, and an externally worn audio processor. The bone conduction implant is called the BONEBRIDGE Bone Conduction Implant (BCI 602) and the externally worn audio processor is called the SAMBA 2 Audio Processor. The BCI 602 consists of two main sections, the coil section and the transducer section. The BCI 602 consists of a magnet surrounded by the receiver coil, the transition, the Bone Conduction Floating Mass Transducer (BC–FMT), and the electronics package in a hermetic housing. The SAMBA 2 Audio Processor is 30.4 mm × 36.4 mm × 10.2 mm and weighs 9.3 g, including the battery and magnet (strength 1). It

has an 18-band digital equalizer, 18 independent compression channels, and an audio frequency range of 250 Hz to 8 kHz. The audio processor is powered by a non-rechargeable 675 zinc-air button cell with a nominal 1.4-volt supply and 600 mA-Hrs of capacity offering the user up to 133 hours (8 to 10 days) on a single battery.

The applicant stated that the bone conduction implant is surgically attached to the skull, subcutaneous, and is connected to the external audio processor by transcutaneous magnetic attraction. The external audio processor picks up sound from the environment and converts those sounds to a radiofrequency (RF) signal that that can be transmitted across the skin to the implant. The implant converts the signal to controlled vibrations which are conducted via the skull and perceived as sound. More specifically, the applicant stated that the BCI 602 is activated by placing the external audio processor over the magnet of the BCI 602. The signal and the energy to drive the BC–FMT are transferred via an inductive link to the internal coil, and then relayed to the BC–FMT. The BC–FMT transduces the signal into mechanical vibrations, which are conducted to the skull via the cortical titanium screws. These vibrations stimulate the auditory system through the bone conduction pathway to allow the patient to hear.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted a *de novo* request classifying the BONEBRIDGE as a Class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on July 20, 2018. The BONEBRIDGE is indicated for use in the following patients: (1) Patients 12 years of age or older; and (2) patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 45 dB HL; (3) Bilateral fitting of the BONEBRIDGE is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies; (4) Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (that is, single-sided deafness or ''SSD''). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz); (5) The BONEBRIDGE for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS. Prior to receiving the device, it is recommended that an individual have experience with appropriately fit air conduction or bone conduction hearing aids. We received the application for a new device category for transitional pass-through payment status for the BONEBRIDGE on December 10, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the BONEBRIDGE meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the BONEBRIDGE is integral to the service provided, is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. The applicant also claimed that the BONEBRIDGE 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. Additionally, the BONEBRIDGE is not subject to the hearing aid exclusion at § 411.15(d)(1). The BONEBRIDGE Bone Conduction Implant (BCI 602) component is an osseointegrated implant, surgically attached to the skull that converts a radiofrequency signal from an external audio processor to controlled vibrations which are conducted via the skull to the cochlea. Therefore, we believe the BONEBRIDGE meets the criterion at § 411.15(d)(2)(i) and is not subject to the hearing aid exclusion. In accordance with the Medicare Benefit Policy Manual, Chapter 16 ''General Exclusions from Coverage,'' section 100, certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These include osseointegrated implants, that is, devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer. We believe the BONEBRIDGE device meets the criteria of this benefit category. We are inviting public comments on whether the BONEBRIDGE meets the eligibility criteria at § 419.66(b) as well as the criterion at § 411.15(d)(2)(i).

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.

The applicant stated that the previous category, L8690—Auditory osseointegrated device, includes all internal and external components, which was effective from January 1, 2007-December 31, 2008 did not include the BONEBRIDGE. The applicant stated that at the time the category was established, BONEBRIDGE did not exist and the devices described by the category included auditory osseointegrated implant (AOI) devices or bone-anchored hearing aids (BAHA). The applicant claimed that AOI devices and BAHAs are distinct from the BONEBRIDGE because they are implant systems composed of an external sound processor connected via a percutaneous abutment to a titanium implant that is implanted in the skull. In these devices, the titanium implant protrudes through the skin creating a titanium post, which directly attaches to an external sound processor. The system replaces the function of the middle ear by transmitting mechanical energy from the external transducer/sound processor directly to the titanium implant to the cochlea thereby resulting in better hearing. The applicant stated that the titanium abutment used by percutaneous systems permanently pierce the skin to allow the sound processor to transmit sound and create vibrations within the skull that stimulate the nerve fibers of the inner ear. The applicant also stated that in the percutaneous systems, the external component (sound processor) receives and processes the sound and generates the vibrations.

The applicant claimed that the BONEBRIDGE is a new technology compared to the AOI devices and BAHAs and unlike these devices, it does not use a percutaneous abutment. The applicant described BONEBRIDGE as an active, transcutaneous device that consists of a completely implanted transducer and electronics components, and an externally worn audio processor. The active implant is surgically attached to the skull, is subcutaneous, and is connected to the external audio processor by transcutaneous magnetic attraction. The external audio processor picks up sound from the environment and converts those sounds to a radiofrequency (RF) signal that can be transmitted across the skin to the implant. The implant converts the

signal to controlled vibrations, which are conducted via the skull and perceived as sound. The applicant proposed the device pass-through category descriptor ''Auditory osseointegrated device, transcutaneous, with implanted transducer and radiofrequency link to external sound processor'' and suggested that L8690 be revised to read, ''Auditory osseointegrated device, percutaneous, includes all internal and external components''. The applicant stated that the Cochlear Osia™ 2 System, which also submitted a device pass-through application for CY 2022, would also be described by the proposed additional category.

We believe that the BONEBRIDGE is described by L8690—Auditory osseointegrated device, includes all internal and external components. The applicant has noted differences between the BONEBRIDGE and the devices that were described by L8690, specifically percutaneous, auditory osseointegrated devices, regarding the connection between the implanted transducer and the external audio processor (percutaneous abutment vs. transcutaneous magnetic attraction). However, we believe that there is a similar mechanism of action for all these devices specifically, vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear). Further, we believe that the broad descriptor for L8690 of ''Auditory osseointegrated device, includes all internal and external components'' includes the applicant's device.

We are inviting public comment on whether the BONEBRIDGE meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. With respect to the substantial clinical improvement criterion, the applicant stated that the BONEBRIDGE represents a substantial clinical improvement because it provides a reduced rate of device-related complications and a more rapid beneficial resolution of the disease process treated because of the use of the device compared to currently available treatments. The applicant submitted six studies to support these claims. The applicant also submitted references for four retrospective case studies of complications with percutaneous devices, specifically bone-anchored hearing aids, including infections, pain, soft tissue hypertrophy, loss of osseointegration, and need for further surgery. These studies did not involve the applicant's device.

In support of the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments, the applicant submitted a white paper that reviewed the literature reporting on safety outcomes in bone conduction implants authored by the manufacturer of the BONEBRIDGE, MED–EL.[37] The review included five products used to treat conductive hearing loss, mixed hearing loss or single side deafness, which were either percutaneous systems that had an abutment that permanently pierced through the skin or transcutaneous systems without permanent skin penetration. The authors further defined the products as either active or passive, depending on the placement of the vibrating (or active) device component. According to the authors, active bone conduction systems, the active device component, is located within the implantable part of the system. According to the authors, passive bone conduction systems, the vibrating device component, is located outside of the skull.[38]

The literature review compared the safety outcomes of the BAHA Connect and the Ponto, (passive, percutaneous systems,) the BONEBRIDGE, (an active, transcutaneous systems), and the Sophono Alpha and the BAHA Attract, (passive, transcutaneous systems). In total, 156 studies were included in the literature review. There were seven studies with 234 patients reported on the Ponto, thirteen studies with 175 patients reported on the BONEBRIDGE, twelve publications with 143 patients reported on the Sophono Alpha, seven studies reported on the BAHA Attract system with 114 patients, and 117 studies reported on the BAHA Connect system with a total of 6,965 patients. Of all reported adverse events, 38 percent were major and 62 percent were minor. Major adverse events reported in the review included revision surgery, explantation, removal at patient request, implant loss, implant device failure, skin revision surgery or skin infection. Minor adverse events included skin infections, soft tissue reactions, and healing difficulties. The results showed that 9.8 percent of patients using the BONEBRIDGE system experienced an adverse event (major or minor), compared to 68.4 percent of BAHA Attract patients, 46.9 percent of Sophono Alpha patients, 44.0 percent of Ponto system patients and 51.7 percent of BAHA Connect patients. When comparing the percentage of patients who experienced a major adverse event, 2.9 percent of BONEBRIDGE patients had a major adverse event compared to 1.8 percent of BAHA Attract patients, 4.2 percent of Sophono Alpha patients, 5.1 percent of Ponto system patients, and 21.1 percent of BAHA Connect patients.

To support the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments, the applicant also submitted a systematic review of the current literature on safety, efficacy and subjective benefit after implantation with the BONEBRIDGE device.[39] The systematic review assessed 39 publications and included randomized controlled trials, clinical controlled trials and cohort studies, case series and case reports investigating subjective and objective outcomes. In the 39 publications included in the review, 487 participants were evaluated; 303 participants had conductive hearing loss, 67 participants had mixed hearing loss, and 53 participants had single-sided deafness. The mean age of the patients in the included studies was 35.6 ± 16.9 years. Using the guidelines available from the Cochrane Collaboration, a search strategy and review protocol was developed using PubMed (MEDLINE) and Cochrane databases to identify all publications on the BONEBRIDGE from 2012 to October 31, 2018. The researchers excluded studies that assessed a device or treatment other than the BONEBRIDGE, did not include human participants, focused on a type of hearing loss other than the losses that BONEBRIDGE is indicated for (that is, conductive hearing loss, mixed hearing loss or single-sided deafness), did not report on safety or performance/quality of life data, were not related to hearing loss or treatment thereof, lacked

[37] MED–EL Medical Electronics. (2019). Safety outcomes of bone conduction implants: A systematic review [White paper].

[38] Ibid.

[39] Magele, A., Schoerg, P., Stanek, B. *et al.* (2019). Active transcutaneous bone conduction hearing implants: Systematic review and meta-analysis. *PLoS ONE* 14(9); e0221484 *https://doi.org/10.1371/journal.pone.0221484.*

sufficient information for evaluation, and included overlapping samples.

The outcomes extracted from the studies were assessed via meta-analysis. The safety of the device was assessed by collecting information on complications during surgery and adverse events in the postoperative period. Of the 39 identified studies, there were 25 studies that reported on safety during a mean period of 11.7 months (range 3–36 months). The reported complications were categorized into minor and major complications, with a major complication described as requiring surgical attention leading to revision surgery or explantation. Minor complications included skin edema or erythema, skin infections, and hematomas. Out of 286 ears implanted with the device, there were no complications in 259 ears (90.6 percent). Minor complications occurred in 22 ears (7.7 percent) over a cumulative period of reported mean follow-up of 12.7 years (mean: 11.7 months ± 4.5). Major complications occurred in three studies comprising five ears (1.7 percent).[40]

The applicant submitted an additional study by Schmerber, et al. to support the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments.[41] The study of 28 participants was a multicenter, prospective study with intra-subject measurements with the purpose of the study to validate the safety and efficacy of the BONEBRIDGE 12 months after implementation. The study included nine university hospitals, seven in France and two in Belgium. Sixteen participants with conductive or mixed hearing loss with bone-conduction hearing thresholds under the upper limit of 45 dB HL for each frequency from 500 to 4,000 Hz, and 12 participants with SSD (contralateral hearing within normal range) were enrolled in the study. Three of the 28 participants (with mixed or conductive hearing loss) did not complete the study; one requested that the device be removed (due to ''severe psychological problems'') and two were lost to follow up. The skin safety of the participants was evaluated by the surgeon who implanted the device up to 12 months post-operatively using an ordinal scale (''very good'', ''good'', ''acceptable'', ''bad skin condition'') and a visual analogue scale (between 1 and 10 from ''very bad'' to ''excellent'') to rate cutaneous tolerance. In the study, no complications or device failures occurred, no revision surgery was necessary and no skin injury was reported. The scoring was judged as 'excellent' or 'good' for all subjects (n = 25), corresponding to scores 8 to 10 on the scale. No complication (0 percent) was observed [95 percent confidence interval = (0 percent − 14.9 percent)]. The authors stated that there was a lower rate of complications for the BONEBRIDGE device compared to percutaneous systems, like the BAHA, whose complication rate was up to 24 percent in a large series of 602 ears and a revision surgery rate of 12 percent.[42 43]

The applicant also submitted a study by Siegel et al. as evidence to support the claim that the BONEBRIDGE reduced the rate of device-related complications compared to currently available treatments.[44] The study was a retrospective review that included 37 adult patients with conductive/mixed hearing loss who met the indications for use and were implanted with BONEBRIDGE over a five-year period from April 2013 to May 2018. Patient charts were reviewed for surgical outcomes and complications over the 6-year period. The mean time of follow-up was 32 months (range: 9–71 months). There were no events of surgical complications in the patients included in the study, specifically no instances of dural injury, cerebrospinal fluid (CSF) leak, or intracranial bleeding. There were also no skin complications and no postoperative symptoms of tinnitus/vertigo or dizziness.[45]

In support of the assertion that the use of BONEBRIDGE resulted in a more rapid beneficial resolution of the disease process compared to currently available treatments, the applicant also referenced the Magele et al., and Siegel et al. studies as well as a study conducted by Yang et al.[46 47 48]

As previously noted, the Magele et al. study assessed 39 publications that included 487 participants; 303 participants had conductive hearing loss, 67 participants had mixed hearing loss, and 53 participants had single-sided deafness.[49] Functional gain was available for analysis from 14 articles and was measured as the difference between unaided and aided (with the BONEBRIDGE) warble tone thresholds. On average, functional gain of 32.7 dB ± 16 dB was observed. Overall, the results showed a 30.89 dB (95 percent CI 27.53 dB − 34.24 dB) improvement at speech presentation level; for the 30 conductive hearing loss patients, the improvement was 39.48 dB (95 percent CI 35.25 dB − 43.71 dB); for the mixed hearing loss group, the improvement was 29.08 dB (95 percent CI 26.32 dB − 31.83 dB) and the improvement was 28.94 dB (95 percent CI 16.92 dB − 40.96 dB) for the 10 subjects with single-sided deafness.

The applicant also noted the study by Siegel et al. to support the claim that the use of BONEBRIDGE resulted in a more rapid beneficial resolution of the disease process compared to currently available treatments.[50] As previously stated, in this study, 37 adult patients with conductive/mixed hearing loss who met the indications for use were implanted with BONEBRIDGE over a six-year period. The patients' charts were reviewed for surgical outcomes and complications over the six-year period. Preoperative air conduction (AC), preoperative bone conduction (BC), and 3-month postoperative aided thresholds were recorded. Speech perception was assessed using two different tests, consonant-nucleus-consonant (CNC) words and AzBio sentences. Pure-tone averages (PTAs; measured at 0.5, 1.0, 2.0 and 3.0 kHz), air-bone gap (ABG), and functional gain (FG) were calculated. The preoperative air-bone gap was calculated as the difference between AC thresholds and BC thresholds of the implanted ear. The postoperative ABG was calculated as the difference between the preoperative BC and postoperative BONEBRIDGE aided thresholds measured at 3 months postoperatively. Functional gain was

[40] Ibid.

[41] Schmerber, S., Deguine, O., Marx, M. *et al.* (2017). Safety and effectiveness of the Bonebridge transcutaneous direct-drive bone-conduction hearing implant at 1-year device use. *Eur Arch Otorhinolaryngol* 274: 1835–1851 doi 10.1007/s00405–016–4228–6.

[42] Schmerber, S., Deguine, O., Marx, M. *et al.* (2017). Safety and effectiveness of the Bonebridge transcutaneous direct-drive bone-conduction hearing implant at 1-year device use. *Eur Arch Otorhinolaryngol* 274: 1835–1851 doi 10.1007/s00405–016–4228–6.

[43] Hobson, J.C., Roper, A.J., Andrew, R., Rothera, M.P., Hill, P., Green, K.M. (2010) Complications of bone-anchored hearing aid implantation. *J Laryngol Otol* 124(2):132–136. doi:10.1017/S0022215109991708.

[44] Siegel, L.H., You, P., Zimmerman, K. *et al.* (2020). Active transcutaneous bone conduction implant: Adiometric outcomes following a novel middle fossa approach with self-drilling screws. *Otol Neurotol* 41(5): 605–613. *doi: 10.1097/MAO.0000000000002597.*

[45] Siegel, L.H., You, P., Zimmerman, K. *et al.* (2020). Active transcutaneous bone conduction implant: Audiometric outcomes following a novel middle fossa approach with self-drilling screws. *Otol Neurotol* 41(5): 605–613. *doi: 10.1097/MAO.0000000000002597.*

[46] Ibid.

[47] Ibid.

[48] Ibid.

[49] Ibid.

[50] Siegel, L.H., You, P., Zimmerman, K. *et al.* (2020). Active transcutaneous bone conduction implant: Audiometric outcomes following a novel middle fossa approach with self-drilling screws. *Otol Neurotol* 41(5): 605–613. *doi: 10.1097/MAO.0000000000002597.*

calculated as the difference between preoperative AC thresholds and BONEBRIDGE aided thresholds measured 3 months postoperatively.

The results of this study showed audiological improvement in the 37 patients with a functional gain (averaged over 4 frequencies, 500 kHz to 3,000 kHz) of 40.3 dB (± 19.0 dB) for air conduction 3 months postoperatively. The difference between the average air to bone conduction gap fell from 44.9 dB preoperative to 4.6 dB three months after surgery. The postoperative air conduction thresholds for the 21 patients with mixed hearing loss ranged between 30–40 dB and the air conduction thresholds for the 16 patients with conductive hearing loss ranged between 20–30 dB. For patients with mixed hearing loss, nearly a full ABG closure was achieved at all frequencies by 3 months postoperatively.

In the same study, speech perception testing was available for 21 patients (57 percent). At activation, mean speech perception results for CNC words (13 patients) and AzBio sentences (14 patients) were 79 and 93 percent, respectively. At six months postoperatively, CNC words (17 patients) and AzBio sentences (21 patients) were 81 and 93 percent, respectively. The authors stated that the results of the study were comparable with what has been accomplished using traditional percutaneous conduction devices and passive transcutaneous bone conduction devices.

Lastly, to support the claim that the use of the BONEBRIDGE resulted in a more rapid beneficial resolution of the disease process, the applicant submitted a study that compared the use of the BONEBRIDGE with a non-implantable bone conduction hearing aid (BCHA).[51] This single center, prospective study involved 100 patients in Beijing, China with bilateral congenital microtia-atresia (CMA). The patients had a mean age of 11.9 ± 6.0 years old at the time the BONEBRIDGE was implanted. All patients had worn the passive bone anchored hearing aid for at least a year prior to the implantation of the BONEBRIDGE and patients were tested an average of 25 weeks after surgery. Measured outcomes in the study included sound field thresholds (SFT), functional gain (FG) [aided threshold minus the unaided threshold], word recognition, speech reception thresholds (SRT), preoperative and postoperative bone and air conduction and patient subjective satisfaction. Bone conduction of pure tones at any frequency did not change significantly from preoperative to postoperative testing. The mean bone-conduction pure-tone threshold (PTA) before implantation was 8.7 ± 6.1 dB HL and after surgery was 8.9 ± 5.6 dB HL ($p > .745$, paired t-test). Furthermore, bone conduction did not significantly change at any frequency after surgery ($p > .05$, t-test). The mean SFT of the BONEBRIDGE (61.6 ± 7.1 dB HL) was significantly higher than the BCHA (31.3 ± 6.1 dB HL) (paired t-test, $p < .001$) and the SFT was significantly better with BONEBRIDGE at 500, 1,000, 2,000, and 4,000 Hz sound frequencies (paired t-test, $p < .002$). Further, the FG of the BONEBRIDGE (31.2 ± 9.5 dB HL) was significantly better than the FG of the BCHA (26.5 ± 10.3 dB HL) (paired t-test, $p < .001$). The FG measured at 250 Hz in the two aided conditions had less improvement compared to other frequencies ($p < .001$). A comparison of BCHA and BONEBRIDGE resulted in a significant difference in word recognition (68.0 percent for monosyllabic words and 79.0 percent for disyllabic words with the BCHA vs. 78.0 percent for monosyllabic and 84.0 percent for disyllabic words with the BONEBRIDGE) in favor of the BONEBRIDGE ($p < .001$).

Regarding the applicant's evidence of substantial clinical improvement, we note that the studies submitted did not involve a direct comparison to other currently available treatments, namely percutaneous or passive, transcutaneous auditory osseointegrated devices. Therefore, it was difficult to determine whether the BONEBRIDGE provided a substantial clinical improvement over existing devices. Also, the studies submitted included a small number of participants which may affect the generalizability of the data provided in support of the device.

In the white paper by MED–EL, the authors compared the complication rates associated with various studies that differed by design, population characteristics and follow-up time. We are not confident that differences seen or elucidated by the applicant are due to the differences in treatments or instead due to differences in study characteristics. Additionally, although the overall, both major and minor, adverse event ratio was significantly lower for the BONEBRIDGE device (9.8 percent) versus other bone conduction hearing devices in the study, when comparing the percent of patients who experienced a major adverse event, BONEBRIDGE patients had a major adverse event (2.9 percent) that was more comparable to other devices included in the paper. With regard to the Yang et al. study, given the young age of the patients and the congenital nature of the hearing loss being treated, we are concerned that these results may not be generalizable to the Medicare population, which tends to be significantly older in age and potentially less likely to have hearing loss related to congenital causes. We invite public comments on whether BONEBRIDGE meets 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. The applicant stated that there were no specific CPT codes that currently describe the implantation of BONEBRIDGE. To demonstrate that the requested category met the cost criterion, the applicant submitted the HCPCS codes used to describe implantation of a percutaneous device, included in the following Table 22.

[51] Yang, J., Chen, P., Zhao, C. *et al.* 2020. Audiological and subjective outcomes of 100 implanted transcutaneous bone conduction devices and preoperative bone conduction hearing aids in patients with bilateral microtia-atresia. *Acta Oto-Laryngologica* 140(6): 667–673 *https://doi.org/10.1080/00016489.2020.1762929.*

TABLE 22 – HCPCS CODES REPORTED WITH BONEBRIDGE

HCPCS Code	Short Descriptor	SI	APC
69714	Implant temple bone w/stimul	J1	5115
69715	Temple bne implnt w/stimulat	J1	5116
69717	Temple bone implant revision	J1	5114
69718	Revise temple bone implant	J1	5115

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5115—Level 5 Musculoskeletal Procedures, which had a CY 2020 payment rate of $11,900.71 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). HCPCS code 69714 had a device offset amount of $7,742.60 at the time the application was received. According to the applicant, the cost of the BONEBRIDGE is $11,500.

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 $11,500 for BONEBRIDGE is 97 percent of the applicable APC payment amount for the service related to the category of devices of $11,900.71 (($11,500/$11,900.71) × 100 = 96.6 percent). Therefore, we believe BONEBRIDGE meets the first cost significance requirement.

The second cost significance requirement, 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 $11,500 for BONEBRIDGE is 149 percent of the cost of the device-related portion of the APC payment amount for the related service of $7,742.60 (($11,500/$7,742.60) × 100 = 148.5 percent). Therefore, we believe that BONEBRIDGE meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $11,500 for BONEBRIDGE and the portion of the APC payment amount for the device of $7,742.60 is 31.6 percent of the APC payment amount for the related service of $11,900.71 ((($11,500 − $7,742.60)/$11,900.71) × 100 = 31.6 percent). Therefore, we believe that BONEBRIDGE meets the third cost significance requirement.

We invite public comment on whether BONEBRIDGE meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(3) Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific Corporation submitted an application for device pass-through status for the Eluvia™ Drug-Eluting Vascular Stent System (Eluvia™ system) for CY 2022. According to the applicant, the Eluvia™ system is a combination product composed of an implantable endoprosthesis, a non-bonded freely dispersed drug layer (a formulation of paclitaxel contained in a polymer matrix), and a stent delivery system indicated for the treatment of symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery (PPA).

According to the applicant, the Eluvia™ system stent is a laser-cut self-expanding stent composed of nickel titanium alloy with radiopaque markers made of tantalum on the proximal and distal ends. The applicant states that the 6-French delivery system is a triaxial design with an outer shaft to stabilize the stent delivery system, a middle shaft to protect and constrain the stent, and an inner shaft to provide a guidewire lumen. The delivery system is compatible with 0.035 in (0.89mm) guidewires and is offered in two working lengths (75 and 130 cm).

According to the applicant, peripheral artery disease (PAD) occurs when fatty or calcified material (plaque) builds up in the walls of the arteries and makes them narrower, thus restricting blood flow. The applicant asserts that when this occurs, the muscles in the legs cannot get enough blood and oxygen, especially during exertion such as exercise or walking. According to the applicant, the main symptoms of PAD are pain, burning sensation, or general discomfort in the muscles of the feet, calves, or thighs. As the disease progresses, plaque accumulation may significantly reduce blood flow through the arteries, resulting in claudication and increasing disability, with severe cases often leading to amputation of the affected limb. The applicant states that according to the Centers for Disease Control and Prevention approximately 8.5 million people age 40 and older in the United States have PAD, including 6–26 percent of individuals older than age 60.[52] According to the applicant,

[52] Centers for Disease Control and Prevention. *https://www.cdc.gov/heartdisease/pad.htm.*

PAD disproportionately affects African American and American Indian populations [53] and nonrevascularized lower extremity PAD is among the most common causes of lower extremity amputation.

According to the applicant, the Eluvia™ system is designed to restore blood flow in the peripheral arteries above the knee, specifically the superficial femoral artery and proximal popliteal artery. The applicant states that the stent features a unique drug-polymer combination intended to facilitate sustained elution of the drug paclitaxel that can prevent narrowing (restenosis) of the vessel. The applicant adds that restenosis is often the cause of pain and disability for patients diagnosed with PAD.

The applicant asserts that no other endovascular technologies that are approved for the treatment of PAD provide sustained elution of a drug over at least 12 months to prevent restenosis. According to the applicant, two of the most common endovascular treatments for PAD are angioplasty and stenting. The applicant states that following an intervention within the SFA or PPA, these arteries elicit a healing response that leads to restenosis starting with inflammation, followed by smooth muscle cell proliferation and matrix formation.[54] According to the applicant, because of the unique mechanical forces in the SFA and PPA, the restenotic process can continue well beyond 12 months from the initial intervention. The applicant asserts the Eluvia™ system is designed to elute anti-restenotic drug paclitaxel beyond 12 months, which is longer than the two-month duration of drug applied from drug-coated balloons and the drug-coated stent Zilver PTX.

With respect to the newness criterion at § 419.66(b)(1), the Eluvia™ system received FDA premarket approval (PMA) on September 18, 2018. The application for a new device category for transitional pass-through payment status for the Eluvia™ system was received on February 26, 2021, which is within 3 years of the date of the initial FDA approval or clearance. We invite public comments on whether the Eluvia™ system meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Eluvia™ system is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically impacted or inserted. The applicant also claimed that the Eluvia™ 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. Previously, we invited public comment and subsequently determined that Eluvia™ system device meets the eligibility criterion (84 FR 61286). We invite public comments on whether the Eluvia™ system continues to meet the eligibility criterion at § 419.66(b).

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 Eluvia™ system. The applicant proposed a category descriptor for the Eluvia™ system of ''Stent, non-coronary, polymer matrix, minimum 12-month sustained drug release, with delivery system.'' Previously, we invited public comment and subsequently determined that Eluvia™ system device meets the device category eligibility criterion. For a complete discussion of comments received, please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61286–61287). We invite public comments on whether the Eluvia™ system continues to meet this 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 claims the Eluvia™ system provides a substantial clinical improvement over existing technologies for the following reasons: (1) The Eluvia™ system achieves superior primary patency; (2) the Eluvia™ system achieves reduced lesion revascularization, leading to a reduced rate of subsequent therapeutic interventions at one year and a statistically significant reduction of target lesion revascularization (TLR) at two years; (3) the Eluvia™ system decreases the number of future hospitalizations or physician visits; (4) the Eluvia™ system reduces hospital readmission rates; (5) Eluvia reduces the rate of device related complications; and (6) the Eluvia™ system achieves similar functional outcomes and quality of life index values while associated with half the rate of TLRs.

Many of the assertions made by the applicant are derived from the IMPERIAL trial which is reported in three citations supplied by the applicant.[55] [56] [57] We discuss results from the MAJESTIC study and then these publications from the IMPERIAL study to provide context for the assertions made by the applicant.

The first article, by Müller-Hülsbeck et al., discusses the three-year results of the MAJESTIC study, the first-in-human prospective, single-arm, multicenter, clinical trial involving 57 patients with symptomatic lower limb ischemia and lesions in the superficial femoral artery or proximal popliteal artery.[58] Patients who were treated with the Eluvia™ system were followed for a three-year time period during which they took acetylsalicylic acid as an antiplatelet therapy. At 24 months, patients received a duplex ultrasound, ankle-brachial index, and Rutherford classification at a clinical visit. At 36 months patients completed a telephone or clinical visit which included adverse event and antiplatelet medication assessments. The authors report that long-term results from the MAJESTIC study of the Eluvia™ system continue to demonstrate good technical and clinical outcomes (assessed through 2 years) and

[53] Virani SS, et al. AHA Statistical Update: Heart Disease and Stroke Statistics—2020 Update, A Report from the American Heart Association. Circulation. 2020;141:e139–e596.

[54] Forrester JS, et al. A paradigm for restenosis based on cell biology: Clues for the development of new preventive therapies. J Am Coll Cardiol. 1991 Mar 1;17(3):758–69.

[55] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[56] Müller-Hülsbeck S et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44:368–375.

[57] Golzar J et al. Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: One-Year Outcomes of the Single-Arm IMPERIAL Long Lesion Substudy of the Eluvia Drug-Eluting Stent. Journal of Endovascular Therapy. 2020;27(2):296–303.

[58] Müller-Hülsbeck S, Keirse K, Zeller T, Schroe H, Diaz-Cartelle J. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Followup. Cardiovasc Interv Ther. 2017;40(12):1832–1838.

a low reintervention rate (through 3 years).

The second article, by Gray et al., discusses the IMPERIAL trial, a prospective randomized (2:1) (Eluvia™ system vs. Zilver PTX), single-blind, non-inferiority study in 465 patients with symptomatic lower-limb ischemia manifesting as claudication with atherosclerotic lesions in the native superficial femoral artery or proximal popliteal artery across 65 centers and multiple countries.[59] Of the 465 patients enrolled, 309 were assigned to the Eluvia™ system and 156 were assigned to Zilver PTX. The authors state the overall sample size in the randomised trial was selected to preserve adequate statistical power for non-inferiority testing of the primary efficacy and safety endpoints at a prespecified, one-sided significance level of 5 percent for each, without adjustment for multiplicity.

The authors state baseline demographic, clinical, and angiographic characteristics were similar between the two study groups, indicative of successful randomization. The primary efficacy endpoint of the trial was primary vessel patency at 12 months which was a binary endpoint based on a duplex ultrasound peak systolic velocity ratio of 2.4 or lower in the absence of clinically driven target lesion revascularization or bypass of the target lesion. Secondary endpoints at 12 months were technical success, procedural success, adverse events, stent integrity, major adverse events, and clinical outcomes. The authors note that the funder of the study was involved in study design, data collection, data analysis, data interpretation, and writing of the report. To identify statistically meaningful results for the non-inferiority test, the authors used a test such as the Farrington-Manning method, to estimate the lower bound for the 95 percent CI of the difference between treatment groups.[60] According to the authors, if this lower bound was greater than the non-inferiority margin of −10 percent, the Eluvia™ system would be considered non-inferior to Zilver PTX in terms of device efficacy. For all other statistical comparisons, the authors used a p value of less than 0.05 as indicative of a significant difference.

According to the authors, the primary non-inferiority analyses were done when 409 patients (276 in the Eluvia group and 133 in the Zilver PTX group) had completed 12 months of follow-up or had a primary efficacy or safety endpoint event.[61] Primary patency was observed for 231 (87 percent) of 266 patients in the Eluvia™ system group and for 106 (82 percent) of 130 patients in the Zilver PTX stent group (difference 5.3 percent [one-sided lower bound of 95 percent CI −0.66]; p<0·0001). 259 (95 percent) of 273 patients in the Eluvia group and 121 (91 percent) of 133 patients in the Zilver PTX group had not had a major adverse event at 12 months (difference 3.9 percent [one-sided lower bound of 95 percent CI −0·46]; p<0·0001). According to the authors, superiority of the Eluvia™ system over Zilver PTX (primary patency in 86.8 percent vs. 77.5 percent respectively, p = 0.0144) was met in the post-hoc analysis of 12 month primary patency data in the full-analysis cohort. The authors summarize by stating the proportions of patients with stent thrombosis or clinically driven target lesion revascularisation in the Eluvia stent group were about half those in the Zilver PTX group while both groups showed improvements in clinical symptoms and walking function and the occurrence of stent fracture was low.[62]

The third article, by Golzar et al, discusses the one-year follow up of the single-arm long lesion substudy portion of the IMPERIAL trial.[63] Fifty patients were enrolled in the study where 20 patients had diabetes, 16 were current smokers, 35 had moderately or severely calcified lesions, and 16 lesions were total occlusions. To be eligible, patients needed a lesion ranging from 140 mm to 190 mm which required two overlapping Eluvia stents. At 12 months, no deaths, stent thrombosis, or target limb amputation had occurred. The primary patency rate was 87.0 percent at 12 months which exceeded the 60 percent performance goal. Forty-three patients (91 percent) had Rutherford category improvement without the need for TLR. The authors concluded that one year patency with the Eluvia™ system was independent of lesion length.

The fourth article, by Müller-Hülsbeck et al., discusses the two-year follow up to the IMPERIAL trial.[64] The authors found that through 24 months, the patency rates and Rutherford category improvements were largely sustained, with a significantly lower clinically driven TLR rate for Eluvia versus Zilver PTX at 2 years. At two years the TLR rate for patients treated with Eluvia was 12.7 percent as compared to patients treated with Zilver PTX at 20.1 percent (P = 0.0495). As with the previous citation, both study arms show sustained clinical improvement (that is improvement in Rutherford classification by one or more categories as compared with baseline and without TLR) of 84.4 percent for patients treated with Eluvia and 78.2 percent for patients treated with Zilver PTX (p = 0.140). For all-cause mortality, Eluvia (7.1 percent) and Zilver PTX (8.3 percent) did not statistically differ (p = 0.6649). The authors conclude that the IMPERIAL trial provides support for the benefit of drug-eluting treatment in this population.

According to the applicant, the Eluvia™ system achieves superior primary patency compared to Zilver PTX. The applicant states that, based on the IMPERIAL trial, the Eluvia™ system demonstrated superior primary patency over Zilver PTX, 86.8 percent vs. 77.5 percent respectively (p=0.0144) based on pre-specific post-hoc analysis. The applicant further states that at 12 months, the Eluvia™ system had greater primary patency than Zilver PTX at 88.5 percent vs. 79.5 percent respectively (p=0.0119). According to the applicant, these results are consistent with the 96.4 percent primary patency rate at 12 months in the MAJESTIC study, the single-arm first-in-human study of the Eluvia™ system.[65] Furthermore, in regard to this point, the applicant asserts among patients 65 and older, the primary patency rate in the Eluvia™ system was 92.6 percent

[59] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[60] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[61] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[62] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[63] Golzar J et al. Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: One-Year Outcomes of the Single-Arm IMPERIAL Long Lesion Substudy of the Eluvia Drug-Eluting Stent. Journal of Endovascular Therapy. 2020;27(2):296–303.

[64] Müller-Hülsbeck S et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44:368–375.

[65] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

compared to 75.0 percent in Zilver PTX (p=0.0386). Lastly, the application states that among 50 patients with an average lesion length of 162.8 mm (long lesions), each treated with two Eluvia stents, there was a 12 month primary patency of 87 percent and a TLR of 6.5 percent.[66]

According to the applicant, the Eluvia™ system reduced subsequent therapeutic interventions at one year and a reduction of target lesion revascularization at two years. Based on the IMPERIAL trial, the applicant asserts the Eluvia™ system achieved a substantial reduction in re-intervention with a target lesion revascularization (TLR) of 4.5 percent compared to 9.0 percent (p=0.0672) in the Zilver PTX group.[67] The applicant states that at two years the Eluvia™ system had a statistically significantly lower rate of TLRs than Zilver PTX of 12.7 percent vs. 20.1 percent respectively (p=0.0495).[68] The applicant notes that the published analysis presented in this application has a slightly different clinically-driven TLR rate at two years than internal analysis provided in the Eluvia CY 2020 device pass-through application (12.7 percent and 20.1 percent (p=0.0495) vs. 12.9 percent and 20.5 percent (p=0.0472), respectively). We note that the applicant provides a table which compares TLR rates between the Eluvia™ system and Zilver PTX by all patients 65 and older, US patients 65 and older, and patients with diabetes.

The applicant asserts that patients treated with the Eluvia™ system required fewer days of hospital care than in the Zilver PTX group. According to the applicant, patients treated with the Eluvia™ system had fewer days in the hospital as compared to Zilver PTX for all adverse events (13.9 vs. 17.7 respectively), TLR (2.8 vs. 7.1 respectively), and procedure and device related adverse events (2.7 vs. 4.5 respectively). We note that statistical significance was not assessed.

The applicant asserts that patients treated with the Eluvia™ system had reduced hospital readmission rates compared to those treated with Zilver PTX at 12 months at 3.9 percent and 7.1 percent respectively (p=0.1369).[69]

The applicant asserts that while rates of adverse events were similar in total between treatment arms in the IMPERIAL trial, device-related adverse-events were reported in 8 percent of patients treated with the Eluvia™ system as compared to 14 percent of patients treated with Zilver PTX.[70]

Lastly, the applicant asserts that the Eluvia™ system is able to achieve similar functional outcomes to Zilver PTX while associated with half the rate of TLRs. The applicant states while functional outcomes appear similar between the Eluvia Stent System and Zilver PTX groups at 12 months, these improvements for the Zilver PTX group are associated with twice as many TLRs to achieve similar EQ–5D index values.[71] The applicant provides multiple tables which show similar improvements in walking, distance, speed, stair climbing, and health related quality of life (EQ–5D) between the Eluvia™ system and Zilver PTX.

For a complete discussion of the applicant's previous submission regarding substantial clinical improvement please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61287–61292). We note that we did not approve the Eluvia™ system for CY 2020 device transitional payment due to the potential increased long-term mortality signal that the FDA was at the time evaluating. We further note that in the FY 2021 IPPS/LTCH final rule (85 FR 58657), we stated that the FDA August 7, 2019 update, which concluded that the benefits of paclitaxel-coated devices (for example, reduced reinterventions) should be considered in individual patients along with potential risks (for example, late mortality) as well as for individual patients judged to be at particularly high risk for restenosis and repeat femoropopliteal interventions, clinicians may determine that the benefits of using a paclitaxel-coated device outweigh the risk of late mortality. The applicant asserts that the Eluvia™ system has demonstrated substantial clinical improvement over Zilver PTX in the IMPERIAL trial to include no increase in all-cause mortality. In response to this new information, we no longer have concerns regarding the increased long-term mortality signal we described in the CY 2020 OPPS/ASC final rule with comment period.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61289) we noted that the IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for noninferiority and not superiority. Therefore, we were concerned that results showing primary patency at 12 months may not be valid given the study design. In response, the applicant stated that a non-inferiority study is consistent with accepted research methodology and is typical of many head-to-head trials of medical devices. For the complete response please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61290). We invite public comments on whether the Eluvia™ Drug-Eluting Vascular Stent System meets the substantial clinical improvement criterion with respect to a finding of substantial clinical improvement for the Eluvia™ system.

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 Eluvia™ system would be reported with the HCPCS codes in the following Table 23:

[66] Golzar J et al. Effectiveness and Safety of a Paclitaxel-Eluting Stent for Superficial Femoral Artery Lesions up to 190 mm: One-Year Outcomes of the Single-Arm IMPERIAL Long Lesion Substudy of the Eluvia Drug-Eluting Stent. Journal of Endovascular Therapy. 2020;27(2):296–303.

[67] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[68] Müller-Hülsbeck S et al. Two-Year Efficacy and Safety Results from the IMPERIAL Randomized Study of the Eluvia Polymer-Coated Drug-Eluting Stent and the Zilver PTX Polymer-free Drug-Coated Stent. Cardiovasc Intervent Radiol. 2021;44:368–375. Published online 22 November 2020.

[69] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[70] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

[71] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018;392:1541–51.

TABLE 23 – HCPCS CODES REPORTED WITH ELUVIA ™ SYSTEM

HCPCS Code	Short Descriptor	SI	APC
37226	Fem/popl revasc w/ stent	J1	5193
37227	Fem/popl revasc stnt & ather	J1	5194

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5193—Level 3 Endovascular Procedures, which had a CY 2021 payment rate of $10,042.94 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). HCPCS code 37226 had a device offset amount of $4,843.71 at the time the application was received.

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 Eluvia™ system is 56 percent of the applicable APC payment amount for the service related to the category of devices of $10,042.94. Therefore, we believe the Eluvia™ system meets the first cost significance requirement.

The second cost significance requirement, 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 for the Eluvia™ system is 117 percent of the cost of the device-related portion of the APC payment amount for the related service of $4,843.71. Therefore, we do not believe that the Eluvia™ system meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 for the Eluvia™ system and the portion of the APC payment amount for the device of $4,843.71 is 8 percent of the APC payment amount for the related service of $10,042.94. Therefore, we do not believe that Eluvia™ system meets the third cost significance requirement.

We invite public comment on whether the Eluvia™ system meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(4) Cochlear™ Osia® 2 System

Cochlear Americas submitted an application for a new device category for transitional pass-through payment status for the Cochlear™ Osia® 2 System (hereinafter referred to as the Osia® 2 System) by the December 2020 quarterly deadline for CY 2022. The Osia® 2 System is a transcutaneous, active auditory osseointegrated device that replaces the function of the middle ear by providing mechanical energy to the cochlea. According to the applicant, the device consists of four components including: (1) An external sound processor, the Osia 2 Sound Processor; (2) the Osia OSI200 Implant Piezo Power™ transducer; (3) the BI300 osseointegrated implant for anchoring and single point transmission; and (4) a fixation screw for attaching the OSI200 implant to the BI300 implant which is implanted in the skull.

The external sound processor captures environmental sounds and converts the sound signal into a digital signal transmitted as a radiofrequency. The external sound processor also contains a magnet and a battery (rechargeable 675 zinc air button 1.4Volt; 600 mA-hrs capacity). The magnets couple the external and internal components across the skin. The transducer (Piezo Power™) detects the radiofrequency signals after they pass through the intact skin and transforms the signal to vibrations, which are then transmitted to the bone-implanted fixation screw. The screw vibrates the skull bone (temporal portion) which stimulates the cochlea (inner ear) to transmit the information to the brain so that the vibrations are perceived as sounds. The implanted portion is 7.2 cm × 3 cm × 0.49 cm. The system has a fitting range of 55 dB sensory neural hearing loss. The applicant stated that unlike hearing aids, which make sounds louder, an auditory osseointegrated device, such as the Osia® 2 System can improve clarity of hearing and improve hearing at higher frequencies.

With respect to the newness criterion at § 419.66(b)(1), the Osia® 2 System received FDA 510(k) clearance on November 15, 2019, based on a determination of substantial equivalence to a legally marketed predicate device. The Osia® 2 System is intended for the following patients and indications: (1) Patients 12 years of age or older; (2) patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 55 dBHL; (3) Bilateral fitting of the Osia® 2 System is intended for patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 3 kHz, or less than 15 dB at individual frequencies; (4) patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (that is, single-sided deafness or ''SSD''). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2, and 3 kHz). The Osia® 2 System for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS. Prior to receiving the device, it is recommended that an individual have experience with appropriately fitted air conduction or bone conduction hearing aids.

We received the application for a new device category for transitional pass-through payment status for the Osia® 2 System on December 1, 2020, which is

within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the Osia® 2 System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Osia® 2 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. The applicant also claimed that the Osia® 2 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. Additionally, the Osia® 2 System is not subject to the hearing aid exclusion at § 411.15(d)(1). As described in the application, the implanted components of the Osia® 2 System consist of a piezoelectric transducer (OSI200) that is attached directly to an osseointegrated implant (BI300) with a fixation screw. Sound received by an external processor (the Osia® 2 System) is converted to a digital radiofrequency signal which is received and transformed into mechanical vibrations by the OSI200 implant, which are transferred directly to the BI300 osseointegrated implant. These vibrations are conducted via the skull to the cochlea. Therefore, we believe the Osia® 2 System meets the criterion at § 411.15(d)(2)(i) and is not subject to the hearing aid exclusion.

In accordance with the Medicare Benefit Policy Manual, Chapter 16 ''General Exclusions from Coverage,'' § 100, certain devices that produce perception of sound by replacing the function of the middle ear, cochlea or auditory nerve are payable by Medicare as prosthetic devices. These include osseointegrated implants, that is, devices implanted in the skull that replace the function of the middle ear and provide mechanical energy to the cochlea via a mechanical transducer. We believe the Osia® 2 System as described by the application meets the criteria for this benefit category. We are inviting public comments on whether the Osia® 2 System meets the eligibility criteria at § 419.66(b) as well as the criterion at § 411.15(d)(2)(i).

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.

The applicant stated that the Osia® 2 System differs significantly from the devices that were included in the previous category for auditory osseointegrated devices (L8690—Auditory osseointegrated device, includes all internal and external components) which was effective from effective from January 1, 2007 through December 31, 2008. The applicant claimed that the devices that were described by this category include a transducer/actuator and sound processor that is worn externally with the transducer/actuator connected to the skull by a percutaneous post or abutment that penetrates the skin. In these devices, the sound processor converts sound into a digital signal which the transducer/actuator converts to vibrations that are transmitted to the skull through the abutment. The vibrations are transmitted directly to the inner ear and are reproduced as sound.

The applicant stated that the Osia® 2 System is distinct from devices with a percutaneous connection between the transducer and the sound processor because the transducer/actuator for the Osia® 2 system is surgically implanted and has a magnetic transcutaneous attachment to the external sound processor. The applicant also claimed that the percutaneously coupled osseointegrated devices included in the previous device pass-through category convert sound to mechanical vibrations in the external sound processor/actuator, then transmit the vibrations to the internal components. The applicant claimed that the Osia® 2 system instead converts the sound to mechanical vibrations after it has reached the internal components. The applicant claimed that the technology to fully implant the transducer/actuator did not exist when the previous device pass-through category was established. The applicant proposed the device pass-through category descriptor ''Auditory osseointegrated device, including implanted transducer/actuator with radiofrequency link to external sound processor''. The applicant stated that the BONEBRIDGE Bone Conduction Implant System, which also submitted a device pass-through application for CY 2022 and is described in this section under number (2) above, would also be described by the proposed additional category.

We believe that the Osia® 2 system is described by L8690—Auditory osseointegrated device, includes all internal and external components. The applicant has noted differences between the Osia® 2 system and the devices that were described by L8690, specifically percutaneous, auditory osseointegrated devices, regarding the connection between the implanted transducer and the external audio processor (percutaneous abutment vs. transcutaneous magnetic attraction) however, we believe that there is a similar mechanism of action for all these devices specifically, vibratory stimulation of the skull to stimulate the receptors in the cochlea (inner ear). Further, we believe that the broad descriptor for L8690 of ''Auditory osseointegrated device, includes all internal and external components'' includes the applicant's device. We are inviting public comment on whether the Osia® 2 system meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. With respect to the substantial clinical improvement criterion, the applicant stated that the Osia® 2 system represents a substantial clinical improvement because it provides a reduced rate of device-related complications compared to currently available treatments. The applicant submitted five references to retrospective case series that studied the long-term complications associated with percutaneous osseointegrated bone conduction hearing devices, specifically bone-anchored hearing aids.[72] [73] [74] [75] [76]

[72] Kraai T, Brown C, Neeff M, Fisher K. Complications of bone-anchored hearing aids in pediatric patients. Int J Pediatr Otorhinolaryngol. 2011 Jun;75(6):749–53.

[73] Badran K, Arya AK, Bunstone D, Mackinnon N. Long-term complications of bone-anchored hearing aids: A 14-year experience. J Laryngol Otol. 2009 Feb;123(2):170–6.

[74] House JW, Kutz JW Jr. Bone-anchored hearing aids: Incidence and management of postoperative complications. Otol Neurotol. 2007 Feb;28(2):213–7.

[75] Asma A, Ubaidah MA, Hasan SS, Wan Fazlina WH, Lim BY, Saim L, Goh BS. Surgical outcome of bone anchored hearing aid (baha) implant surgery: A 10 years experience. Indian J Otolaryngol Head Neck Surg. 2013 Jul;65(3):251–4.

[76] Shirazi MA, Marzo SJ, Leonetti JP. Perioperative complications with the bone-

The applicant stated that complications associated with bone-anchored hearing aids include irritation and/or infection of the skin surrounding the abutment, skin flap necrosis, wound dehiscence, bleeding or hematoma formation, soft tissue overgrowth and persistent pain.[77 78 79 80 81] Additionally, the applicant also submitted five references to clinical studies and case series involving the use of transcutaneous osseointegrated bone conduction hearing devices. Of these five references, three of these studies involved the use of the BONEBRIDGE device and have been previously discussed in this section, one study that involved the use of the BAHA Attract device, and one study that involved the use of the Osia® system, an earlier version of the Osia® 2 system.

In support of their claim that the Osia® 2 system reduced the rate of device-related complications compared to currently available treatments, the applicant submitted a multicenter prospective within-subject study conducted at five centers in Europe, Australia, and USA. This study investigated clinical performance, safety, and benefit of the Osia® system and included 51 adult subjects with mixed and conductive hearing loss (MHL/CHL, n = 37) and single-sided sensorineural deafness (SSD, n = 14). In regard to safety outcomes, patients experienced the following minor adverse events including pain (n = 7), numbness (n = 1), vertigo (n = 3), swelling (n = 3), tension implant site (n = 1), warmth at the SP site (n = 3), headache (n = 3), hematoma/bleeding (n = 2).[82] One participant developed an implant-site infection three days after implantation, which subsequently developed into skin necrosis and dehiscence. The implant had to be removed 55 days after implantation.

We are concerned that the applicant did not submit studies that involved the use of the Osia® 2 system to demonstrate substantial clinical improvement of the device. The applicant submitted one study that investigated the Osia® system that utilizes an earlier model of the device. We are also concerned that the evidence of substantial clinical improvement submitted by the applicant did not directly compare the Osia® 2 system to other currently available treatments, namely percutaneous or passive, transcutaneous auditory osseointegrated devices. Therefore, we are concerned that we are unable to determine a substantial clinical improvement of the Osia 2 system as compared to existing devices. We would be interested in any additional studies that involve the use of the Osia® 2 system and compare the device to other currently available auditory osseointegrated devices. We invite public comments on whether the Osia® 2 system meets 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. The applicant stated that Osia® 2 system would be reported with the HCPCS codes listed in the following Table 24:

TABLE 24 – HCPCS CODES REPORTED WITH OSIA® 2 SYSTEM

HCPCS Code	Short Descriptor	SI	APC
69714	Implant temple bone w/stimul	J1	5115
69715	Temple bne implnt w/stimulat	J1	5116
69717	Temple bone implant revision	J1	5114
69718	Revise temple bone implant	J1	5115

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5115—Level 5 Musculoskeletal Procedures, which had a CY 2020 payment rate of $11,900.71 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). HCPCS code 69714 had a device offset amount of $7,742.60 at the time the application was received.

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 the Osia® 2 system is 88 percent of the applicable APC payment amount for the service related to the category of devices of $11,900.71. Therefore, we believe the Osia® 2 system meets the first cost significance requirement.

The second cost significance requirement, 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 for the Osia® 2 system is 136 percent of the cost of the device-related portion of the APC payment amount for the related

anchored hearing aid. Otolaryngol Head Neck Surg. 2006 Feb;134(2):236–9.

[77] Ibid.

[78] Ibid.

[79] Ibid.

[80] Ibid.

[81] Ibid.

[82] Mylanos, E.A.M., Hua, H., Arndt, S. 2020. Multicenter clinical investigation of a new active osseointegrated steady-state implant system. *Otol Neurotol* 41: 1249–1257.

service of $7,742.60. Therefore, we believe that the Osia® 2 system meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 the Osia® 2 system and the portion of the APC payment amount for the device of $7,742.60 is 23 percent of the APC payment amount for the related service of $11,900.71. Therefore, we believe that the Osia® 2 system meets the third cost significance requirement.

We invite public comment on whether the Osia® 2 system meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(5) Pure-Vu® System

Motus GI submitted an application for a new device category for transitional pass-through payment status for the Pure-Vu® System (Pure-Vu®) for CY 2022. The applicant asserted that the Pure-Vu® System helps to avoid aborted and delayed colonoscopy procedures due to poor visualization of the colon mucosa by creating a unique High Intensity, Pulsed Vortex Irrigation Jet that consists of a mixture of air and water to break-up fecal matter, blood clots, and other debris, and scrub the walls of the colon while simultaneously removing the debris through two suction channels. The applicant stated that the suction channels have a sensor to detect the formation of a clog in the channels, triggering the system to automatically purge and then revert to suction mode once the channel is clear. According to the applicant, this combination of the agitation of the fluid in the colon via the pulsed vortex irrigation and simultaneous removal of the debris allows the physician to visualize the colon and achieve a successful colonoscopy or other advanced procedure through the colonoscope even if the patient is not properly prepped and has debris either blocking the ability to navigate the colon or covering the colon wall obscuring the mucosa and any pathology that may be present. The applicant asserted that the constant volume suction pumps do not cause the colon to collapse, which allows the physician to continue to navigate the colon while cleansing and avoids the need to constantly insufflate the colon, which may be required with other colonoscopy irrigation systems.

The applicant stated that the Pure-Vu® System is comprised of a workstation that controls the function of the system, a disposable oversleeve that is mounted on a colonoscope and inserted into the patient, and a disposable connector with tubing (umbilical tubing with main connector) that provides the interface between the workstation, the oversleeve, and off the shelf waste containers.

The applicant explained that the workstation has two main functions: cleansing via irrigation and evacuation, and acting as the user interface of the system. The applicant explained that the irrigation into the colon is achieved by an electrical pump that supplies pressurized gas (air) and a peristaltic pump that supplies the liquid (water or saline). According to the applicant, the pressurized gas and liquid flow through the ''main connector'' and are mixed upon entry into the umbilical tubing that connects to the oversleeve. The applicant explained that the gas pressure and flow are controlled via regulators and the flow is adjusted up or down depending on the cleansing mode selected. The applicant stated that a foot pedal connected to the user interface activates the main functions of the system so that the user's hands are free to perform the colonoscope procedure in a standard fashion.

The applicant stated that the evacuation mode (also referred to as suction) removes fecal matter and fluids out of the colon. The applicant noted that the evacuation function is active during cleansing so that fluid is inserted and removed from the colon simultaneously. The applicant explained that the evacuation pumps are designed in a manner that prevents the colon from collapsing when suctioning, which facilitates the ability to simultaneously irrigate and evacuate the colon. According to the applicant, during evacuation, the system continuously monitors the pressure in the evacuation channels of the oversleeve and if the pressure drops below pre-set limits the pumps will automatically reverse the flow. The applicant explained that the clog sensor triggers the system to automatically purge the material out of the channel and back into the colon where it can be further emulsified by the Pulsed Vortex Irrigation Jet, and then automatically reverts back into evacuation mode once the channel is cleared. The applicant stated that the evacuation (suction) that drains fecal matter and fluids out of the colon is generated by peristaltic pumps that can rotate in both directions, either to evacuate fluids and fecal matter from the colon through the evacuation tubes and into a waste container, or while in the reverse direction, to purge the evacuation tubes. The applicant claimed the suction created by this type of pump creates a constant volume draw of material from the colon and therefore prevents the colon from collapsing rapidly. According to the applicant, purging of evacuation tubes may be activated in two ways: the purging cycle is automatically activated when low pressure is noted by the evacuation-line sensor (it is also activated for the first 0.5 seconds when evacuation is activated to make sure the line is clear from the start); or a manual purge may be activated by the user by pushing the ''manual purge'' button on the foot pedal. The applicant claimed the pressure-sensing channel is kept patent by using an air perfusion mechanism where an electrical pump is used to perfuse air through the main connector and into the oversleeve, while the sensor located in the workstation calculates the pressure via sensing of the channel.

The applicant explained the Pure-Vu® System is loaded over a colonoscope and that the colonoscope with the Pure-Vu® Oversleeve is advanced through the colon in the same manner as a standard colonoscopy. The applicant stated that the body of the oversleeve consists of inner and outer sleeves with tubes intended for providing fluid path for the cleansing irrigation (2X), the evacuation of fluids (2X), the evacuation sensor (1X) and that the flexible head is at the distal end of the oversleeve and is designed to align with the colonoscope's distal end in a consistent orientation. The applicant explained that the distal cleansing and evacuation head contains the irrigation ports, evacuation openings, and a sensing port. According to the applicant, the system gives the physician the control to cleanse the colon as needed based on visual feedback from the colonoscope to make sure they have an unobstructed view of the colon mucosa to detect and treat any pathology. The applicant noted that since the Pure-Vu® System does not interfere with the working channel of the colonoscope, the physician is able to perform all diagnostic or therapeutic interventions in a standard fashion with an unobstructed field of view.

With respect to the newness criterion at § 419.66(b)(1), the Pure-Vu® System first received FDA 510(k) clearance on September 22, 2016 under 510(k) number K60015. Per the applicant, this initial device was very cumbersome to set up and required direct support from

the company and therefore was not viable for a small company with limited resources to market the device. The applicant noted that the initial device could have been sold starting on January 27, 2017 when the first device came off the manufacturing line. Per the applicant, the device was allocated for clinical evaluations but 10 institutions throughout the country did purchase the device outside of any true clinical study, mostly based on the fact that physicians wanted to try the product prior to committing to a clinical trial. The applicant further noted that minor modifications were made to the Pure-Vu® System in additional 510(k) clearances dated December 12, 2017 and June 21, 2018. The current marketed Pure-Vu® System was then granted 510(k) clearance on June 6, 2019 under 510(k) number K191220. Per the applicant, this clearance changed the entire set-up of the device, redesigned the user interface, and reduced the size, among other changes. According to the applicant, this updated version was commercially available as of September 19, 2019. We have not identified an existing pass-through payment category that describes the Pure-Vu® System. We are inviting public comment on whether the Pure-Vu® System meets the device category criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Pure-Vu® is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted temporarily. The applicant also claimed that Pure-Vu® 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. We are inviting public comments on whether Pure-Vu® meets the eligibility criteria at § 419.66(b).

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 Pure-Vu®. We are inviting public comment on whether Pure-Vu® meets the device category criterion.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. The applicant stated that Pure-Vu® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant submitted studies that examined the impact of Pure-Vu® on endoscopic hemostasis outcomes, rebleeding occurrence, and mortality. We note that the applicant has applied for the New Technology Add-on Payment in the FY 2022 IPPS/LTCH proposed rule (86 FR 25299 through 25304).

According to the applicant, the Pure-Vu® System offers the ability to achieve rapid beneficial resolution of the disease process treatment by achieving rapid and full visualization of the colon, which will improve diagnostic yield and the effectiveness of treatment of diseases of the bowel. The applicant claimed that Pure-Vu® is indicated for use in emergent issues such as acute lower gastrointestinal (GI) bleeding, unknown abdominal pain, foreign body removal, chronic disease management, and preventive medicine such as screening and surveillance. The applicant states these procedures are typically performed using a colonoscope to visualize the colon and provide a conduit to deliver therapeutic treatments. According to the applicant, the current standard of care requires the colon to be cleansed to ensure the success of any procedure. The applicant asserts that in the case where pre-procedural preparations are not adequate to achieve proper visualization, current technology provides limited ability to remove debris from the colon during the procedure to facilitate the process. The applicant states that regardless of indication, the bowel preparation remains the constant across patients who may have a wide range of comorbidities which may limit patient tolerability. According to the applicant the consumption of a purgative and the dietary restriction to be on clear liquids for approximately 24 hours can be problematic for the diabetic and elderly populations.[83]

In support of its application, the applicant submitted three outpatient clinical studies to demonstrate the Pure-Vu® System's capability to convert patients to adequate preparation where preparation was previously inadequate and the visualization was poor based on the Boston Bowel Preparation Scale (BBPS). In the first study, Perez J., et al. conducted an outpatient prospective pilot study using the Pure-Vu® System.[84] The study observed 50 patients with poorly prepared colons undergoing colonoscopy at two outpatient clinical sites in Spain and Israel, respectively. The applicant claimed study patients underwent a reduced bowel preparation consisting of the following: No dried fruits, seeds, or nuts starting 2 days before the colonoscopy, a clear liquid diet starting 18 to 24 hours before colonoscopy, and a split dose of 20mg oral bisacodyl. The study found the number of patients with an adequate cleansing level (BBPS ≥2 in each colon segment) increased significantly from 31 percent (15/49) prior to use of the Pure-Vu System (baseline) to 98 percent (48/49) after use of the Pure-Vu® System ($P<0.001$), with no serious adverse events reported.

In the second study provided by the applicant, van Keulen, et al. also conducted a single-arm, prospective study on 47 patients with a median age of 61 years in the outpatient setting in the Netherlands using the Pure-Vu® System.[85] Within the study, cecal intubation was achieved in 46/47 patients. This multicenter feasibility study found that the Pure-Vu® System significantly improved the proportion of patients with adequate bowel cleansing from 19.1 percent prior to the use of the Pure-Vu® System to 97.9 percent after its use ($P<0.001$) and median BBPS score (from 3.0 [IQR 0.0–5.0] to 9.0 [IQR 8.0–9.0]).

In the third study provided by the applicant that directly evaluated the Pure-Vu® System in a clinical setting, Bertiger G., et al. performed a United States-based single center, prospective,

[83] Parra-Blanco A, Ruiz A, Alvarez-Lobos M, Amoros A, Gana JC, Ibanez P, et al. Achieving the best bowel preparation for colonoscopy. World J Gastroenterol. 2014;20(47):17709–26.

[84] Perez Jimenez J, Diego Bermudez L, Gralnek IM, Martin Herrera L, Libes M. An Intraprocedural Endoscopic Cleansing Device for Achieving Adequate Colon Preparation in Poorly Prepped Patients. J Clin Gastroenterol. 2019;53(7):530–4.

[85] Van Keulen KE, Neumann H, Schattenberg JM, Van Esch AAJ, Kievit W, Spaander MCW, Siersema PD. A novel device for intracolonoscopy cleansing of inadequately prepared colonoscopy patients: A feasibility study. Endoscopy. 2019 Jan;51(1):85–92. doi: 10.1055/a–0632–1927. Epub 2018 Jul 11.

outpatient study investigating regimes of reduced outpatient bowel preparations, which included low doses of over-the-counter laxatives, and eliminating the typical 24 hour clear liquid diet restriction, which was replaced by a low residue diet the day before the procedure.[86] In this study, 46 of a possible 49 patients received a colonoscopy, 8 of which took the over-the-counter laxative (''MiraLAX arm''), 21 patients ingested two doses of 7.5oz Magnesium Citrate (MgC) each taken with 19.5oz of clear liquid (''Mag Citrate 15oz arm''), and 18 patients ingested 2 doses of 5oz MgC taken with 16oz of clear liquid (''Mag Citrate 10oz arm''). Of the 46 subjects, 59 percent were males and there was a mean age of 61 ± 9.48 years. The study found that each of the 3 study arms revealed significant differences in BBPS score between the baseline preparation and post-cleansing via Pure-Vu®. All the preparation regimens resulted in inadequately prepped colons. Comparing the mean BBPS rating for both pre- and post-Pure-Vu® use, the MiraLAX arm was inferior ($P<0.05$) to both Mag Citrate arms. For the MiraLAX arm, the mean BBPS Score improved from 1.50 to 8.63. For the Mag Citrate 15oz arm, the mean BBPS score improved from 3.62 to 8.95. For the Mag Citrate 10oz arm, the mean BBPS Score improved from 4.76 to 9.0.

The applicant also provided a self-sponsored, U.S.-based, multicenter, prospective, single arm study in the inpatient setting, analyzing 94 patients, 65 of which (68 percent) had a GI bleed.[87] Of the 94 patients (41 percent females/59 percent males), the mean age was 62 years. According to the applicant, the study's primary endpoint was the rate of improved bowel cleansing level from baseline to after use of the Pure-Vu® System per colon segment using the BBPS. The BBPS score was recorded for each colorectal segment (left colon, transverse colon, and right colon segments) both prior to (baseline) and after colon cleansing with the Pure-Vu® System. An adequate cleansing level was *a priori* defined as a BBPS ≥2 in all evaluated colon segments. The study found that in 79 of the 94 patients (84 percent), the physician was able to successfully diagnose or rule out a GI bleed in the colon per the patients' colonoscopy indication using only the Pure-Vu® System. The analysis showed statistically significant visualization improvement in each colon segment after Pure-Vu® use with a mean BBPS score in the descending colon, sigmoid, and rectum of 1.74 pre-Pure-Vu® use and 2.89 post-Pure-Vu® use ($P<0.001$); in the transverse colon of 1.74 pre-Pure-Vu® use and 2.91 post Pure-Vu® use ($P<0.001$); and the ascending colon and cecum of 1.50 pre-Pure-Vu® use and 2.86 post Pure-Vu® use ($P<0.001$). The study found only 2 percent of cases where the diagnosis could not be achieved due to inadequate preparation. Overall, the 84 (89.4 percent) patients that received the Pure-Vu® System within the study improved BBPS scores from 38 percent (95 percent CI 28, 49) to 96 percent (95 percent CI 90, 99) in segments evaluated. The study noted one procedure related perforation which required surgical repair, and the patient was discharged 48 hours post operatively and recovered fully.

In addition to the previously discussed studies, the applicant also submitted two case studies to highlight the various clinical presentations of lower gastrointestinal bleed (LGIB) with the use of the Pure-Vu® System. In the first case, the applicant described a patient with a history of scleroderma and chronic constipation who was referred for a surveillance colonoscopy after a prior endoscopic mucosal resection due to a large polyp. The applicant states this was the patient's third colonoscopy in twelve months due to a history of poor preparation in the prior exams. Despite an aggressive prep regime, the applicant states the patient still had solid stool and debris throughout the colon. The applicant states the Pure-Vu® system was used extensively and the physician was able to fully cleanse the colon during which the physician was able to uncover a poorly defined over 1 cm sessile serrated polyp that could not be appreciated before cleansing with Pure-Vu®. The applicant states a successful polypectomy was performed.

In the second case, the applicant described a patient presenting with hemorrhagic shock and acute kidney injury six days after a colonoscopy where nine polyps were removed, including two polyps greater than 2cm. The applicant states angiographic control of the bleeding was not considered because of the patient's acute kidney injury with a rising creatinine. According to the applicant, the physician elected to use Pure-Vu® to immediately exam the patient without any preparation doing a bedside colonoscopy in the ICU. The applicant states, the physician was able to cleanse the colon, locate the source of the bleed and create hemostasis by placing two clips on the bleed. According to the applicant, the entire colon was visualized to confirm there were no other sources of bleeding, the physician was able to downgrade the patient out of the ICU that same day, and the patient was discharged from the hospital the following day.

The applicant concludes that based on the provided evidence, Pure-Vu® has the ability to improve adenoma detection rates which can reduce the rate of colorectal cancer (CRC) and diagnose and treat emergent patients in a more expeditious fashion by removing the need to have successful pre-procedural preparation that can take time and be very burdensome to the most needy and fragile patients. According to the applicant, Pure-Vu® can minimize the number of aborted and early repeat colonoscopies that carry inherent risks and add unnecessary costs to the healthcare system.

Based on the evidence submitted with the application, we have the following observations. While the studies provided in support of the Pure-Vu® System measure improvement of bowel preparation using the BBPS, the applicant did not provide data indicating that the improved BBPS directly leads to improved clinical outcomes (for example, reduction of blood loss in LGIB or reduction of missed polyps) based on use of the Pure-Vu® System. Additionally, we note that the applicant has not provided any studies comparing the efficacy of the Pure-Vu® System to other existing methods or products for irrigation in support of its claims that the product is superior at removing debris from the colon while simultaneously preventing the colon from collapsing, allowing use of the working channel, or improving outcomes. Furthermore, we note that many of the provided studies were based on small sample sizes, which may affect the quality and reliability of the data provided in support of the technology.

In addition, we note that it is unclear whether this device would have less utility in the outpatient setting as compared to the inpatient setting, given that patients will typically have time to adequately prepare for scheduled outpatient procedures. We further note that this device may not be broadly applicable in the outpatient setting and are seeking comment for situations in which this device will have a substantial clinical benefit for patients

[86] Bertiger, Gerald MD Optimizing the Preparation Regimen Prior to Colonoscopy Procedure With the Pure-Vu® System, American Journal of Gastroenterology: October 2018—Volume 113—Issue—p S119–S120.

[87] Helmut Neumann ML, Tim Zimmermann, Gabriel Lang, Jason B. Samarasena, Seth A. Gross, Bhaumik Brahmbhatt, Haleh Pazwash, Vladimir Kushnir. Evaluation of bowel cleansing efficacy in hospitalized patient population using the pure-vu system. Gastrointestinal Endoscopy. 2019;89(6).

or subpopulations of patients. For instance, in the outpatient setting, we are not certain that it would be appropriate to use this device in the case of a patient with a poorly prepared bowel as opposed to simply rescheduling the appointment.

Lastly, we note that the Helmut et al. study noted one procedure-related perforation which required surgical repair and we invite public comments regarding the concern of procedure-related perforation.[88] Based upon the evidence presented, we are inviting public comments on whether the Pure-Vu® meets 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. The applicant stated that Pure-Vu® would be reported with the HCPCS codes listed in the following Table 25:

TABLE 25 – HCPCS CODES REPORTED WITH PURE-VU®

HCPCS Code	Short Descriptor	SI	APC
45378	Diagnostic colonoscopy	T	5311
45379	Colonoscopy w/fb removal	T	5312
45380	Colonoscopy and biopsy	T	5312
45381	Colonoscopy submucous njx	T	5312
45382	Colonoscopy w/control bleed	T	5312
45384	Colonoscopy w/lesion removal	T	5312
45385	Colonoscopy w/lesion removal	T	5312
45388	Colonoscopy w/ablation	T	5312
45390	Colonoscopy w/resection	J1	5313

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5311—Level 1 Lower GI Procedures, which had a CY 2020 payment rate of $763.88 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). HCPCS code 45378 had a device offset amount of $1.07 at the time the application was received. According to the applicant, the cost of the Pure-Vu® is $975.

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 $975 for Pure-Vu® is 128 percent of the applicable APC payment amount for the service related to the category of devices of $763.80 (($975/$763.88) × 100 = 127.7 percent). Therefore, we believe Pure-Vu® meets the first cost significance requirement.

The second cost significance requirement, 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 $975 for Pure-Vu® is 91,122 percent of the cost of the device-related portion of the APC payment amount for the related service of $1.07 (($975/$1.07) × 100 = 91,121.5 percent). Therefore, we believe that Pure-Vu® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $975 for Pure-Vu® and the portion of the APC payment amount for the device of $1.07 is 128 percent of the APC payment amount for the related service of $763.88 ((($975 − $1.07)/$763.80) × 100 = 127.5 percent). Therefore, we believe that Pure-Vu® meets the third cost significance requirement.

We are inviting public comment on whether the Pure-Vu® meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(6) Xenocor Xenoscope™

Xenocor Inc. submitted an application for a new device category for transitional pass-through payment status for the Articulating Xenoscope Laparoscope (hereinafter referred to as the Xenoscope™) by the March 2021 quarterly deadline for CY 2022. The applicant described the Xenoscope™ as a disposable laparoscope which consists of a high-definition camera chip on the tip of a composite shaft, paired with led lights with a handle comprised of a clamshell design and made with molded plastic. The applicant stated that the Xenoscope™ provides visualization in the abdominal and thoracic cavities through small, minimally invasive incisions for diagnostic and therapeutic laparoscopic procedures in a similar fashion to established, reusable versions of laparoscopes. It is paired with an image processing unit, the Xenobox, that can plug into any HD monitor to

[88] Helmut Neumann ML, Tim Zimmermann, Gabriel Lang, Jason B. Samarasena, Seth A. Gross, Bhaumik Brahmbhatt, Haleh Pazwash, Vladimir Kushnir. Evaluation of Bowel Cleansing Efficacy in Hospitalized Patient Population Using the Pure-Vu System. Gastrointestinal Endoscopy. 2019;89(6).

display anatomy in the abdomen, pelvis or chest. The Xenobox uses pre-installed firmware that is upgradable.

The applicant claimed that the Xenoscope™ is the first disposable laparoscope. The applicant also claimed that the use of the Xenoscope™ reduces the number of cords in the operating room, eliminates intraoperative fogging and associated image compromise and eliminates up-front capital enditures associated with reusable laparoscopes.

With respect to the newness criterion, the Xenoscope™ received FDA 510(k) clearance on January 27, 2020, based on a determination of substantial equivalence to a legally marketed predicate device. The Xenoscope™ is indicated for use in diagnostic and therapeutic procedures for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. We received the application for a new device category for transitional pass-through payment status for the Xenoscope™ on August 6, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We are inviting public comments on whether the Xenoscope™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the Xenoscope™ is integral to the service, is used for one patient only, comes in contact with human skin, and is surgically implanted or inserted into the patient. Specifically, the applicant explained that the Xenoscope™ is plugged into the Xenobox image processing unit (which is connected to an HD monitor and an A/C power source). A surgeon then makes a small incision and a trocar (tube-like device with a seal to maintain abdominal pressure) is inserted to gain access to the body cavity. The Xenoscope™ is then inserted through the trocar in order to provide a full view of the anatomy for diagnostic and therapeutic procedures.

The applicant also claimed the Xenoscope™ 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. We are inviting public comments on whether the Xenoscope™ meets the eligibility criteria at § 419.66(b).

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. The applicant described the Xenoscope™ as disposable laparoscope. The applicant reported that it does not believe that the Xenoscope™ is described by an existing category and requested category descriptor ''Single-use laparoscopes.'' The applicant also stated that the currently existing category, C1748—Endoscope, single-use (that is, disposable), upper gi, imaging/illumination device (insertable), did not describe this device because it is limited to single-use duodenoscopes inserted orally, to reach the small intestine versus minimally invasive abdominal surgery (laparoscopy). We have not identified an existing pass-through payment category that is applicable to the Xenoscope™. We are inviting public comments on this issue.

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) 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; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization.

With respect to the substantial clinical improvement criterion, the applicant stated that the Xenoscope™ provides a substantial clinical improvement over reusable laparoscopes because of its single-use nature. Specifically, the applicant claimed, that because the Xenoscope™ is a disposable, single-use device, the Xenoscope™ provides for less risk of scope-related cross-contamination and infection from improperly handled or reprocessed scopes compared to traditional laparoscopy.

The applicant also claimed that the Xenoscope™ includes a fog-free scope and provides a substantial clinical improvement over currently available laparoscopes which, according to the applicant, fog often, and can put patients at risk for surgical errors and more time under anesthesia. Additionally, the applicant claimed that the Xenoscope™ reaches 104 degrees Fahrenheit at the tip, eliminating risk of patient burns and drape fires associated with hotter Xenon bulbs used in currently available laparoscopes.

Lastly, that applicant stated that there can be significant economic benefits through the use of the Xenoscope™ due to the processing costs and up-front capital expenditures required for reusable laparoscopes.

In support of the assertion that the Xenoscope™ reduces the risk of cross-contamination from improperly cleaned reusable laparoscopic instruments, the applicant referenced two articles. The first article was published in 2002 and describes the problem of surgical site infection (SSI), the Centers for Disease Control (CDC) guidelines for SSI, and some cases of SSI related to improper cleaning of reusable laparoscopic instruments. The article also discusses practices to avoid these infections.[89] The applicant also submitted a draft of a manuscript titled ''Novel Laparoscopic System for Quality Improvement and Increased Efficiency'' that summarizes some of the evidence that laparoscopy, in general, is superior to open surgical approaches in terms of pain management and infection risk.[90]

In support of the claim that the Xenoscope™ eliminates the risk of patient burns and drape fires associated with Xenon bulbs used by currently available laparoscopes, the applicant submitted two articles. The first was an article published in 2011 that discusses the problem of laparoscopic related burn injuries and a potential solution using Active Electrode Monitoring (AEM).[91] AEM instruments reportedly use a ''shielded and monitored'' design to prevent the risk of stray energy burn injury from insulation failure and capacitive coupling. According to the article, the AEM technology is currently licensed by Intuitive Surgical's da Vinci® Surgical Systems. The applicant does not compare the Xenoscope™ to AEM technology in terms of burn injury reduction. The second article examined the variation and extent of thermal injuries that could be induced by laparoscopic light sources to porcine tissue. In the study, the maximum temperature at the tip of the optical cable varied between 119.5 degrees C and 268.6 degrees C. When surgical

[89] Hewitt, A. (2002, November 1). *Laparoscopic Instruments: Handle with Care.* Infection Control Today. *https://www.infectioncontroltoday.com/view/laparoscopic-instruments-handle-care.*

[90] Elliott, K.W. & Heilbraun, E. (2020). *Novel Laparoscopic System for Quality Improvement and Increased Efficiency.* Manuscript submitted for publication.

[91] Encision Inc. (2011, April 1*). Method of Reducing Stray Energy Burns in Laparoscopic Surgery.* Medical Design Briefs. *https://www.medicaldesignbriefs.com/component/content/article/mdb/tech-briefs/9500.*

drapes were exposed to the tip of the light source, the time to char was 3–6 seconds. The degree and volume of injury increased with longer exposure times, and significant injury was recorded with the optical cable 3 mm from the skin.[92]

In support of the claim that there could be significant economic benefits realized through the use the Xenoscope™ compared to reusable laparoscopes, the applicant also referenced the manuscript entitled ''Novel Laparoscopic System for Quality Improvement and Increased Efficiency''.[93] In this study, a three-page survey was created to collect data regarding laparoscope-related practices and costs. The survey was completed by three different institutions, including an ambulatory surgery center (ASC), a rural hospital and a suburban hospital. The sites provided the capital equipment cost required at the time of purchase at their facility which ranged from $837,184 to $2,786,348. The average cost per use for one surgical procedure involving a reusable laparoscope was $1,019.24 across the three institutions.

We are concerned that the application and the articles submitted as evidence of substantial clinical improvement discuss potential adverse effects from laparoscopic procedures, but do not appear to directly show any clinical improvement that result from the use of the Xenoscope™. The applicant has provided evidence which seems to rely on indirect inferences from other sources of data. The articles provided did not involve the clinical use of the Xenoscope™ and did not compare the device to an appropriate comparator, such as a reusable laparoscope. Therefore, it is difficult to determine whether the Xenoscope™ offers substantial clinical improvement over standard, reusable laparoscopes based on the information provided. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care.

We are invite public comment on whether the Xenoscope™ meets 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. The applicant stated that the Xenoscope™ would be reported with HCPCS codes listed in the following Table 26:

TABLE 26 – HCPCS CODES REPORTED WITH XENOSCOPE™

HCPCS Code	Short Descriptor	SI	APC
49320	Diag laparo separate proc	J1	5361
49321	Laparoscopy biopsy	J1	5361
47562	Laparoscopic cholecystectomy	J1	5361
44970	Laparoscopy appendectomy	J1	5361
49650	Lap ing hernia repair init	J1	5361
49651	Lap ing hernia repair recur	J1	5361
49652	Lap vent/abd hernia repair	J1	5361
58661	Laparoscopy remove adnexa	J1	5361
58570	Tlh uterus 250 g or less	J1	5362
43281	Lap paraesophag hern repair	J1	5362
43282	Lap paraesoph her rpr w/mesh	J1	5362

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5361 Level 1 Laparoscopy and Related Services, which had a CY 2020 payment rate of $4,833.71. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 49320 had a device offset amount of $107.79 at the time the application was received. According to the applicant, the cost of the Xenoscope™ is $1,500.

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 $1,500 for the Xenoscope™ is 31 percent of the applicable APC payment amount for the service related to the category of devices of Xenoscope™ (($1,500/$4,833.71) × 100 = 31.0 percent). Therefore, we believe Xenoscope™ meets the first cost significance requirement.

[92] Hindle, A. K., Brody, F., Hopkins, V., Rosales, G., Gonzalez, F., & Schwartz, A. (2009). Thermal injury secondary to laparoscopic fiber-optic cables. *Surgical endoscopy, 23*(8), 1720–1723. *https://doi.org/10.1007/s00464-008-0219-z.*

[93] Ibid.

The second cost significance requirement, 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 $1,500 for the Xenoscope™ is 1,392 percent of the cost of the device-related portion of the APC payment amount for the related service of $107.79 (($1,500/$107.79) × 100 = 1,391.6 percent). Therefore, we believe that the Xenoscope™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides 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 $1,500 for the Xenoscope™ and the portion of the APC payment amount for the device of $107.79 is 29 percent of the APC payment amount for the related service of $4,833.71 (($1,500 − $107.79)/$4,833.71) = 28.8 percent). Therefore, we believe that the Xenoscope™ meets the third cost significance requirement.

We invite public comment on whether the Xenoscope™ meets the device pass-through payment criteria discussed in this section, including the cost criterion.

B. Proposed 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 CY 2022 OPPS/ASC proposed rule. 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) and is discussed in detail in Section IV.B.3 of this CY 2022 OPPS/ASC proposed rule. 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, under the device-intensive methodology we 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 APC designations 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 their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.B.1.b. of this CY 2022 OPPS/ASC proposed rule 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 CY 2022 OPPS/ASC proposed rule, 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 previously—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 previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard

from stakeholders that the criteria excluded some procedures that stakeholders believed 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 made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed 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 established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified 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 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 that this 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 finalized that device-intensive procedures will 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 (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, 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 FDA in accordance with §§ 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 either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of the 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) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of 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 device that did 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 was not calculated from claims data; instead, it was applied as a default until claims data were 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 devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously 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 modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a 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 policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very ensive 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 or insertion of a device, device-intensive status is 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 CY 2019 OPPS/ASC final rule with comment period, 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 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 (83 FR 58946). 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 policy, claims data from clinically related and similar codes are 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 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 that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. 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 is 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 is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a 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 & 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.

As discussed in Section X.E of this proposed rule, given our concerns regarding CY 2020 data as a result of the COVID–PHE, we are proposing to use CY 2019 claims data to establish CY 2022 prospective rates. While we continue to believe CY 2019 represents the best full year of claims data for ratesetting, we believe our policy of temporarily assigning a higher offset percentage if warranted by additional information would provide a more accurate device offset percentage for certain procedures. Specifically, for procedures that were assigned device-intensive status, but were assigned a default device offset percentage of 31 percent or a device offset percentage based on claims from a clinically-similar code in the absence of CY 2019 claims data, we are proposing to assign a device offset percentage for such procedures based on CY 2020 data if CY 2020 claims information is available. While we believe that CY 2019 claims data is a better basis for CY 2022 OPPS rates overall, because we have specifically noted that we would consider using more recent data than the data available for ratesetting in a given year to determine device offset percentages for services that do not have any claims data in the year used for ratesetting, we believe it would be consistent with this policy for us to use CY 2020 claims data to determine the device offset percentage for services that meet the above criteria.

For CY 2022, our proposal would assign device offset percentages using CY 2020 claims data to the following 11 procedures:

- 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));
- 0414T (Removal and replacement of permanent cardiac contractility modulation system pulse generator only);
- 0511T (Removal and reinsertion of sinus tarsi implant);
- 0587T (Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve);
- 0600T (Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous);
- 0614T (Removal and replacement of substernal implantable defibrillator pulse generator);
- 66987 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris ansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation);
- 66988 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation);
- C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar);
- C9765 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed); and
- C9767 (Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed).

We are soliciting comments on our proposal to establish the CY 2022 device offset percentage using CY 2020 claims data for device-intensive procedures with no claims in the CY 2019 claims data. The full listing of the proposed CY 2022 device-intensive procedures can be found in Addendum P to this CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this proposed rule can be found under supporting documentation for the CY 2022 OPPS/ASC proposed rule on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

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. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is ''Implantable/insertable device, not otherwise classified''.

We are not proposing any changes to this policy for CY 2022.

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 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 a 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 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We are not proposing any changes to our policies regarding payment for no cost/full credit and partial credit devices in CY 2022.

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 noted 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). 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 previously for the policy applied to the procedure described by CPT code 0308T in CY 2016. For CYs 2019 through 2021, we continued our 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 by using the median cost instead of the geometric mean (85 FR 86019).

As discussed in further detail in Section X.C of this proposed rule, we are proposing to establish a universal low volume APC policy for clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims in the claims data used for ratesetting (for CY 2022 rates, this is proposed to be the CY 2019 claim data). For APCs designated as low volume APCs (those with fewer than 100 single claims in the claims year) under our proposed policy, we propose to establish a payment rate using the highest of the median cost, arithmetic mean cost, or the geometric mean cost. In conjunction with our new, broader low volume APC proposal for clinical APCs, brachytherapy APCs, and New Technology APCs, we are proposing to eliminate our payment policy for low-volume device-intensive procedures for CY 2022 and subsequent calendar years. Currently, CPT code 0308T is the only code subject to our low-volume device-intensive policy. Given that our proposed universal low volume APC policy would utilize a greater number of claims and provide additional cost metric alternatives for ratesetting than our existing low-volume device-intensive policy, we believe that the cost and ratesetting issues previously discussed with respect to CPT code 0308T would be appropriately addressed under our broader universal low volume APC proposal.

We are soliciting comments on our proposal to eliminate our payment policy for low-volume device-intensive procedures and address low-volume, device-intensive procedures through our broader proposal to designate low volume APCs among eligible clinical APCs, brachytherapy APCs, and New Technology APCs.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed 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 the proposed rule, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in the proposed rule includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined under section 351 of 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 for rare diseases and conditions, 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 drug as a hospital outpatient service under Medicare Part B. Proposed CY 2022 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to the proposed rule (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 the proposed rule, 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 our 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 our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

2. Transitional Pass-Through Payment Period for 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 drug or biological 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 drug's or biological'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. Notice of drugs whose pass-through payment status is ending during the calendar year will continue to be included in the quarterly OPPS Change Request transmittals.

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2021

There are 25 drugs and biologicals whose pass-through payment status will expire during CY 2021, as listed in Table 27. Most of these drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2018, through December 31, 2020. 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 proposed to be $130 for CY 2022), as discussed further in section V.B.1. of this proposed rule. 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 ASP-based payment amount (which is proposed at ASP+6 percent for non-340B drugs for CY 2022, as discussed further in section V.B.2. of this proposed rule).

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TABLE 27.--DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL EXPIRE BETWEEN MARCH 31, 2021 AND DECEMBER 31, 2021

CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	03/31/2021
J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	03/31/2021
J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	03/31/2021
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	03/31/2021
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	03/31/2021
J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	03/31/2021
J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021
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	03/31/2021
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	03/31/2021
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021

CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	06/30/2021
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	06/30/2021
J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018	06/30/2021
J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021
Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	07/01/2018	06/30/2021
Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	07/0/2018	06/30/2021
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021
Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	09/30/2021
Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	09/30/2021
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9339	01/01/2019	12/31/2021
J0222	Injection, Patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2021
J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021
J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021

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4. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2022

We propose to end pass-through payment status in CY 2022 for 26 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between April 1, 2019, and January 1, 2020, are listed in Table 28. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2022, are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

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 2022, we propose 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 2022. We propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged as described in Section V.B.1.c. under the CY 2022 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is 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 propose that their pass-through payment amount would be equal to ASP+6 percent for CY 2022 minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological as described in section V.A.6. of this proposed rule. We propose this policy 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 propose to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2022 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 2022, consistent with our CY 2021 policy for diagnostic and therapeutic radiopharmaceuticals, we propose 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 2022, we propose to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we propose to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of this proposed rule), the equivalent payment provided to pass-through drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b. of this proposed rule. If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

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TABLE 28: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING DURING CY 2022

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	03/31/2022
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	03/31/2022
J0642	J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	G	9334	01/01/2020	03/31/2022
J1095	J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	03/31/2022
J3031	J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	03/31/2022
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022
J9119	J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	03/31/2022
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022
Q5108	Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	03/31/2022
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022
Q5111	Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	06/30/2022

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0121	J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	06/30/2022
J1096	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	06/30/2022
J1303	J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	06/30/2022
J9036	J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	06/30/2022
J9210	J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	06/30/2022
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022
J3111	J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	09/30/2022
J9356	J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	09/30/2022
C9054	J0691	Injection, lefamulin (xenleta), 1 mg	G	9332	01/01/2020	12/31/2022
C9055	J1632	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022
J9309	J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022

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5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing in CY 2022

We propose to continue pass-through payment status in CY 2022 for 46 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2020, and April 1, 2021, are listed in Table 29. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will continue after December 31, 2022, are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

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 2023, we propose 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 2022. We propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged as described in Section V.B.1.c. under the CY 2022 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is 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 propose that their pass-through payment amount would be equal to ASP+6 percent for CY 2022 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of this proposed rule. We propose this policy 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 propose to continue to update pass-through payment rates on a quarterly basis on our website during CY 2022 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 2022, consistent with our CY 2021 policy for diagnostic and therapeutic radiopharmaceuticals, we propose 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 2023, we propose to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we propose to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of this proposed rule), the equivalent payment provided to pass-through drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b. of this proposed rule. If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that we propose to have pass-through payment status expire after December 31, 2022, are shown in Table 29.

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TABLE 29: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING AFTER CY 2022

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0179	J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
C9056	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
C9053	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
C9057	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9361	04/01/2020	03/31/2023
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
C9058	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
C9059	J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
C9061	J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
C9063	J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
C9122	J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5118	Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	G	9348	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023
C9060	A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9062	J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	9378	10/01/2020	09/30/2023
C9064	J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023
C9065	C9065	Injection, romidepsin, non-lyophilized (e.g. liquid), 1mg	G	9379	10/01/2020	09/30/2023
C9066	J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
C9067	C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023
J9227	J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
Q5112	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	G	9349	10/01/2020	09/30/2023
Q5121	Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023
J1437	J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023
C9068	A9592	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023

CY 2021 HCPCS Code	CY 2022 HCPCS Code	Long Descriptor	CY 2022 Status Indicator	CY 2022 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9069	J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
C9070	J9349	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
C9071	J1427	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
C9072	J1554	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
C9073	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391	01/01/2021	12/31/2023
N/A	J0693	Injection, cefiderocol, 5 mg	G	9380	01/01/2021	12/31/2023
N/A	J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	G	9390	01/01/2021	12/31/2023
N/A	J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023
Q5122	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	12/31/2023
N/A	C9074	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
N/A	J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024

6. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals To Offset Costs Packaged Into APC Groups

Under the regulation 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 the regulation at 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 policy-packaged drugs, which include 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). For CY 2022, as we did in CY 2021, we propose 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 are identified in Table 30.

TABLE 30: PROPOSED APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2022

CY 2022 APC	CY 2022 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

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We propose to continue to post annually on our 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.

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed 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 $130 for CY 2021 (84 FR 61312 through 61313).

Following the CY 2007 methodology, for this CY 2022 OPPS/ASC proposed rule, 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 2022 and rounded the resulting dollar amount ($132.44) to the nearest $5 increment, which yielded a figure of $130. 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 2022 OPPS/ASC proposed rule, based on these calculations using the CY 2007 OPPS methodology, we propose a packaging threshold for CY 2022 of $130.

b. Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals Under the Cost Threshold (''Threshold-Packaged Drugs'')

To determine the proposed CY 2022 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 2019 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2019 claims processed through June 30, 2020 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 propose to continue to package in CY 2022: 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 2022, we use 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 propose for separately payable drugs and biologicals (other than 340B drugs) for CY 2022, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2022 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2020 (data that were used for payment purposes in the physician's office setting, effective April 1, 2021) to determine the proposed rule per day cost. While the CY 2020 ASP data was collected during the PHE, ASP data are not affected by changes in utilization the way non-drug services are for setting payment rates, and so we believe ASP data continues to be representative of the price of drugs in the market. We have continued to use ASP data from CY 2020 to report quarterly drug rates for CY 2020 and CY 2021.

As is our standard methodology, for 2022, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2020 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 are 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, 2021. 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 2019 hospital claims data to determine their per day cost.

We propose to package items with a per day cost less than or equal to $130, and identify items with a per day cost greater than $130 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2019 HCPCS codes that were reported to the CY 2021 HCPCS codes that we display in Addendum B to this proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2022.

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 2022 OPPS/ASC proposed rule, we proposed to use ASP data from the fourth quarter of CY 2020, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2021, along with updated hospital claims data from CY 2019. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this CY 2022 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the final rule with comment period will be based on ASP data from the second quarter of CY 2021. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2021. These payment rates would then be updated in the January 2022 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2022. 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 2019 claims data and update cost report information available for the CY 2022 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drugs' HCPCS codes' packaging status

determined based on the data used for the final rule with comment period. Under such circumstances, 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 2022 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2021. 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 2022, 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 2021 and that are proposed for separate payment in CY 2022, and that then have per day costs equal to or less than the CY 2022 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2022 final rule, would continue to receive separate payment in CY 2022.
- HCPCS codes for drugs and biologicals that were packaged in CY 2021 and that are proposed for separate payment in CY 2022, and that then have per day costs equal to or less than the CY 2022 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2022 final rule, would remain packaged in CY 2022.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2022 but that then have per-day costs greater than the CY 2022 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2022 final rule, would receive separate payment in CY 2022.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through 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).

d. 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 believe 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, we propose 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 2022.

For CY 2022, 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 2019 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 this CY 2022 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 2019 claims data to make the proposed packaging determinations for these drugs: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); 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 1000 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 2022 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2022 drug packaging threshold of $130 (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 2022 is displayed in Table 31.

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TABLE 31: HCPCS CODES TO WHICH THE CY 2022 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2022 HCPCS Code	CY 2022 Long Descriptor	CY 2022 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
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

CY 2022 HCPCS Code	CY 2022 Long Descriptor	CY 2022 Status Indicator (SI)
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 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.[94]

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 this CY 2022 OPPS/ASC proposed rule, 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

[94] 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.*

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 have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2021.

b. Proposed CY 2022 Payment Policy

For 2022, we propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We propose to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent (as described in section V.B.6). We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055) for more information about our current payment policy for drugs and biologicals acquired with a 340B discount.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of 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) of the Act, 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 final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data is not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6-percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). For CYs 2020 and 2021, we adopted a policy 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) (84 FR 61318 and 85 FR 86039). For 2022, we propose to continue to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC 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 propose to apply this provision to non-SCOD separately payable drugs. Because we propose to establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. We propose 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 under 1847A(c)(4). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the payment amount for these drugs (proposed as a rate of WAC minus 22.5 percent) would continue to apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

We propose that payments for separately payable drugs and biologicals would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also propose that the budget neutral weight scalar would not be applied in determining payments for these separately payable drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available via the internet on the CMS website), which illustrate the proposed CY 2022 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 April 1, 2021, or WAC, AWP, or mean unit cost from CY 2019 claims data and updated cost report information available for this proposed rule. In general, these published payment rates are not the same as the actual January 2022 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2022 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2021 (July 1, 2021 through September 30, 2021) will be used to set the payment rates that are released for the quarter beginning in January 2022 near the end of December 2021. In addition, payment rates for drugs and biologicals in Addenda A and B to the proposed rule for which there was no ASP information available for April 2021 are based on mean unit cost in the available CY 2019 claims data. If ASP information becomes available for payment for the quarter beginning in January 2022, 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 the proposed rule (reflecting April 2021 ASP data) that do not have ASP information available for the quarter beginning in January 2022. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2019 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the proposed rule are not for January 2022 payment purposes and are only illustrative of the CY 2022 OPPS payment methodology using the most recently available information at the time of issuance of the proposed rule.

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 is based on the 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 are 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's ASP (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 plus 6 percent of the reference product's ASP. If a biosimilar does not have ASP pricing, but instead has WAC pricing, the WAC pricing add-on of either 3 percent or 6 percent is calculated from the biosimilar's WAC and is not calculated from the WAC price of the reference product.

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the 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 noted that we believed that these changes would better reflect the resources and production costs that biosimilar manufacturers incur. We also stated that we believe 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 explained that 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), 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. This proposal was finalized without modification in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977).

For 2022, we propose to continue our policy 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 propose to continue our current policy of paying for 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

For CY 2022, we propose 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 2022. Therefore, we propose for CY 2022 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 propose to rely on CY 2019 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 2022 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

4. Payment for Blood Clotting Factors

For CY 2021, 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 (85 FR 86041). That is, for CY 2021, 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 2021 updated furnishing fee was $0.238 per unit.

For 2022, we propose 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 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 is 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 are 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 propose 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 our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

We propose 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.

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

For CY 2022, we propose to continue to use the same payment policy as in CY 2021 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 2022 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 proposed rule, which is available via the internet on the CMS website.

6. CY 2022 OPPS Payment Methodology for 340B Purchased Drugs

a. Overview and Background

Under the OPPS, payment rates for drugs are typically based on their average acquisition cost. This payment is governed by section 1847A of the Act, which generally sets a default rate of average sales price (ASP) plus 6 percent for certain drugs; however, the Secretary has statutory authority to adjust that rate under the OPPS. As described below, beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs, which was based on findings of the GAO and MedPAC that hospitals were acquiring drugs at a significant discount under HRSA's 340B Drug Pricing Program. As described in the following sections, in December 2018, the United States District Court for the District of Columbia (the district court) concluded that the Secretary lacks the authority to bring the default rate in line with average acquisition cost unless the Secretary obtains survey data from hospitals on their acquisition costs. On July 10, 2019, the district court entered final judgment. The agency appealed to the United States Court of Appeals for the District of Columbia Circuit (hereinafter referred to as ''the D.C. Circuit''), and on July 31, 2020 the court entered an opinion reversing the district court's judgment in this matter. Following the D.C. Circuit's reversal of the lower's court decision, appellees' petition for panel rehearing and petition for rehearing en banc were denied on October 16, 2020. For CY 2021, CMS continued its policy of paying for drugs and biologicals acquired through the 340B Program at ASP minus 22.5 percent.

On January 10, 2021, the appellees filed a petition for a writ of certiorari in the United States Supreme Court. On July 2, 2021, the Supreme Court granted their petition for a writ of certiorari, and directed the parties to argue whether the petitioners' suit challenging HHS's 340B drugs payment adjustment is precluded by section 1833(t) (12).[95]

Background

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the OPPS payment methodology for drugs and biologicals (hereinafter referred to collectively as ''drugs'') acquired under the 340B Program. We proposed these changes to better, and more accurately, reflect the resources and acquisition costs that these hospitals incur. We stated our belief 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 with pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. We stated that our goal was 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. Congress created the 340B Drug Pricing Program so that the eligible entities, safety net providers, identified in statute, could stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. By

[95] *https://www.supremecourt.gov/orders/courtorders/070221zor_4gc5.pdf*. Accessed July 8, 2021.

design, the 340B Program increases the resources available to these safety net providers by providing discounts on covered outpatient drugs that generate savings that can be used to support patient care or other services. When the program was created, there was an understanding that many of the patients seen by these safety net providers were Medicare and Medicaid beneficiaries. This rule aims to fulfill the goals of different Federal programs, each of which helps ensure access to care for vulnerable populations. Critical access hospitals are not paid under the OPPS, and therefore are not subject to the OPPS payment policy for 340B-acquired drugs. 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 with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79706), we implemented section 603 of the Bipartisan Budget Act of 2015. As a general matter, applicable items and services furnished in certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered outpatient services for purposes of payment under the OPPS and are paid ''under the applicable payment system,'' which is generally the Physician Fee Schedule (PFS). However, consistent with our policy to pay separately payable, covered outpatient drugs and biologicals acquired under the 340B Program at 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, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in non-excepted off-campus PBDs paid under the PFS. We adopted this payment policy effective for CY 2019 and subsequent years.

We clarified in the CY 2019 OPPS/ASC proposed rule (83 FR 37125) that the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and that 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. 340B-acquired drugs that are priced using AWP are paid an adjusted amount of 69.46 percent of AWP. 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.

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, we 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 excepted from the 340B drug payment policy for CY 2018, were 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 were excepted from the 340B payment adjustment. These hospitals were 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 modifiers ''JG'' and ''TB''.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 and adopted a policy 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. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321), we continued the 340B policies that were implemented in CY 2018 and CY 2019.

Our CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs have been the subject of ongoing litigation. On December 27, 2018, in the case of *American Hospital Association, et al.* v. *Azar, et al.,* the district court concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year.[96] In that same decision, the district court recognized the '' 'havoc that piecemeal review of OPPS payment could bring about' in light of the budget neutrality requirement,'' and ordered supplemental briefing on the appropriate remedy.[97] On May 6, 2019, after briefing on remedy, the district court issued an opinion that reiterated that the 2018 rate reduction exceeded the Secretary's authority, and declared that the rate reduction for 2019 (which had been finalized since the Court's initial order was entered) also exceeded his authority.[98] Rather than ordering HHS to pay plaintiffs their alleged underpayments, however, the district court recognized that crafting a remedy is ''no easy task, given Medicare's complexity,'' [99] and initially remanded the issue to HHS to devise an appropriate remedy while also retaining jurisdiction. The district court acknowledged that ''if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services.'' [100] *Id.* at 19. ''And because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect.'' [101]

We respectfully disagreed with the district court's understanding of the scope of the Secretary's adjustment authority. On July 10, 2019, the district court entered final judgment. The agency appealed to the United States Court of Appeals for the District of Columbia Circuit, (hereinafter referred to as ''the D.C. Circuit''), and on July 31, 2020 the court entered an opinion reversing the district court's judgment in this matter. Following the D.C. Circuit's decision, appellees' petition for panel rehearing and petition for rehearing en banc were denied on October 16, 2020. On January of 2021, appellees petitioned the United States Supreme Court for a writ of certiorari. On July 2, 2021, the Court granted the petition.

Before the D.C. Circuit upheld our authority to pay ASP minus 22.5

[96] *American Hosp. Ass'n, et al.* v. *Azar, et al.,* No. 1:18–cv–2084 (D.D.C. Dec. 27, 2018).

[97] *Id.* at 35 (quoting *Amgen, Inc.* v. *Smith,* 357 F.3d 103, 112 (D.C. Cir. 2004) (citations omitted)).

[98] *See* May 6, 2019 Memorandum Opinion, Granting in Part Plaintiffs' Motion for a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS at 10–12.

[99] *Id.* at 13.

[100] *Id.* at 19.

[101] *Id.* (citing Declaration of Elizabeth Richter).

percent, we stated in the CY 2020 OPPS/ASC final rule with comment period that we were taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. Notably, after the CY 2020 OPPS/ASC proposed rule was issued, we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for certain quarters in CY 2018 and 2019. We stated that such survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years if the district court's ruling was upheld on appeal. The district court itself acknowledged that CMS may base the Medicare payment amount on average acquisition cost when survey data are available.[102] No 340B hospital disputed in the rulemakings for CY 2018 and 2019 that the ASP minus 22.5 percent formula was a conservative adjustment that represented the minimum discount that hospitals receive for drugs acquired through the 340B program, which is significant because 340B hospitals have internal data regarding their own drug acquisition costs. We stated in the CY 2020 OPPS/ASC final rule with comment period that we thus anticipated that survey data collected for CY 2018 and 2019 would confirm that the ASP minus 22.5 percent rate is a conservative amount that overcompensates covered entity hospitals for drugs acquired under the 340B program. We also explained that a remedy that relies on such survey data could avoid the complexities referenced in the district court's opinion. For a complete discussion of the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs, we refer readers to the CY 2021 OPPS/ASC Proposed Rule (85 FR 48882 through 48891) and the CY 2021 OPPS/ASC Final Rule with comment period (85 FR 86042 through 86055).

We proposed a payment rate for 340B drugs of ASP minus 28.7 percent based on survey data, and also proposed in the alternative that the agency could continue its current policy of paying ASP minus 22.5 percent for CY 2021. We explained that we adopted the OPPS 340B payment policy based on the average minimum discount for 340B-acquired drugs being approximately ASP minus 22.5 percent. The estimated discount was based on a MedPAC analysis identifying 22.5 percent as a conservative minimum discount that 340B entities receive when they purchase drugs under the 340B program, which we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52496). We emphasized that we continue to believe that ASP minus 22.5 percent is an appropriate payment rate for 340B-acquired drugs under the authority of section 1833(t)(14)(A)(iii)(II) for the reasons we stated when we adopted this policy in CY 2018 (82 FR 59216). We pointed out that on July 31, 2020, the D.C. Circuit reversed the decision of the district court, holding that this interpretation of the statute was reasonable. Therefore, we also proposed in the alternative that the agency could continue the current Medicare payment policy for CY 2021. If adopted, we stated that this proposed policy would continue the current Medicare payment policy for CY 2021.

Based on feedback from stakeholders, we stated that we believed maintaining the current payment policy of paying ASP minus 22.5 percent for 340B drugs was appropriate in order to maintain consistent and reliable payment for these drugs both for the remainder of the PHE and after its conclusion to give hospitals some certainty as to payments for these drugs. We explained that continuing our current policy also gives us more time to conduct further analysis of hospital survey data for potential future use for 340B drug payment. We also noted that any changes to the current 340B payment policy would be adopted through public notice and comment rulemaking.

Finally, we stated that while we believe our methods to conduct the 340B Drug Acquisition Cost Survey, as well as the methodology we used to calculate the proposed average or typical discount received by 340B entities on 340B drugs, are valid, we nonetheless recognize the comments that we received from stakeholders. Utilization of the survey data is complex, and we emphasized that we wish to continue to evaluate how to balance and weigh the use of the survey data, the necessary adjustments to the data, and the weighting and incorporation of ceiling prices—all to determine how best to take the relevant factors into account for potentially using the survey to set Medicare OPPS drug payment policy. We stated that we would continue to assess commenters' feedback as we explore whether survey data should be considered hospital acquisition cost data for purposes of paying for drugs acquired under section 1833(t)(14)(A)(iii)(I).

CY 2022 Proposed 340B Drug Payment Policy

For CY 2022, we are proposing to continue our current policy without modification of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. We are proposing, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, to pay for separately payable Medicare Part B drugs and biologicals (assigned status indicator ''K''), other than vaccines and drugs on pass-through status, 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. We propose to continue our current policy for calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period, and would continue the policy we finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS.

We are also proposing to continue the 340B payment adjustment for WAC-priced drugs, which is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP would continue to be paid an adjusted amount of 69.46 percent of AWP. Additionally, we are proposing to continue to exempt rural sole community hospitals (as described under the regulations at § 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment. These hospitals will continue to report informational modifier ''TB'' for 340B-acquired drugs, and will continue to be paid ASP plus 6 percent. We may revisit our policy to exempt rural SCHs, as well as other hospital types, from the 340B drug payment reduction in future rulemaking.

We are also continuing to require hospitals to use modifiers to identify 340B-acquired drugs. 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 the requirements for use of modifiers ''JG'' and ''TB''. We believe maintaining the current policy of paying ASP minus 22.5 percent for 340B drugs is appropriate given the July 31, 2020 D.C. Circuit decision, which reversed the district court's decision and found that the interpretation of the statute was reasonable when the 340B drug

[102] *See American Hosp. Assoc.* v. *Azar,* 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

payment policy was implemented in CY 2018. We note that any changes to the current 340B payment policy would be adopted through public notice and comment rulemaking.

While we believe the Secretary has discretion to propose a payment rate for 340B drugs based on the 2020 survey results, we also continue to believe that the current payment rate of ASP minus 22.5 percent represents the minimum discount that 340B covered entities receive, which more closely aligns the payment rate with the resources expended by 340B hospitals to acquire such drugs compared to a payment rate of ASP plus 6 percent, while also 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. Additionally, we continue to believe it is important to provide consistency and reliable payment for these drugs both for the remainder of the Public Health Emergency (PHE) and after its conclusion to give hospitals some certainty as to payments for these drugs.

7. High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

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 package 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 earlier 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 2021, the payment rate for APC 5053 (Level 3 Skin Procedures) was $524.17, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,715.36, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $3,522.15. This information also is available in Addenda A and B of the CY 2021 OPPS/ASC final rule with comment period, as issued with the final rule correction notice (86 FR 11428) (the correction notice and corrected Addenda A and B are available via the internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and we propose to continue it for CY 2022. Under the 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). Beginning in CY 2016 and in subsequent years, we adopted a policy where we determined 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. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high cost group. In addition, we assigned 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 (85 FR 86059).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. 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 over $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), 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 did 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 refinements to the existing policies are 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 request 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 final rule with comment period (83 FR 58967 through 58968), we 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 CY 2019 OPPS/ASC final rule with comment period that we were 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.

For CY 2020, we sought more extensive comments on the two policy ideas that generated the most comment from the CY 2019 comment solicitation. One of the ideas was to establish a payment episode between 4 to 12 weeks where a lump-sum payment would be made to cover all of the care services needed to treat the wound. There would be options for either a complexity adjustment or outlier payments for wounds that require a large amount of resources to treat. The other policy idea would be to eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products. Please refer to the CY 2019 OPPS final rule (83 FR 58967 to 58968) and the CY 2020 OPPS final rule (84 FR 61328 to 61331) for a detailed summary and discussion of the comments we received in response to these comment solicitations. We are continuing to consider the comments we received in response to these comment solicitations.

b. Proposals for Packaged Skin Substitutes for CY 2022

For CY 2022, consistent with our policy since CY 2016, we propose 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. Consistent with the methodology as established in the CY 2014 through CY 2018 final rules with comment period, we analyzed CY 2019 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 proposed CY 2022 MUC threshold is $48 per cm^2 (rounded to the nearest $1) and the proposed CY 2022 PDC threshold is $949 (rounded to the nearest $1). We also propose that our definition of skin substitutes includes synthetic skin substitute products in addition to biological skin substitute products as described in section V.B.7.d. of this proposed rule. We also want to clarify that the availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2022, as we did for CY 2021, we propose to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, we propose 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 2022, we propose that any skin substitute product that was assigned to the high cost group in CY 2021 would be assigned to the high cost group for CY 2022, regardless of whether it exceeds or falls below the CY 2022 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For 2022, we propose to continue to assign skin substitutes with pass-through payment status to the high cost category. We propose 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 propose 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 propose to use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We propose to continue to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b. of this proposed rule to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2022 MUC and PDC thresholds. We also propose to continue to include synthetic products in addition to biological products in our description of skin substitutes. 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). For a discussion of how we determined that synthetic skin graft sheet products can be reported with graft skin substitute procedure codes, we refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86064 to 86067). Table 32 displays the final CY 2022 cost category assignment for each skin substitute product.

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TABLE 32: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2022

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Proposed CY 2022 High/Low Cost Assignment
C1849	Skin substitute, synthetic	High	High
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 or omnigraft	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*

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Proposed CY 2022 High/Low Cost Assignment
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 ccm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq 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

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Proposed CY 2022 High/Low Cost Assignment
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 centimeter	Low	Low
Q4167	Truskin, per square centimeter	Low	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Flowcramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	Low	High
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	Low	High
Q4190	Artacent ac 1 sq cm	Low	High

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Proposed CY 2022 High/Low Cost Assignment
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	High
Q4194	Novachor 1 sq cm	High	High*
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 1 sq cm	Low	High
Q4200	Skin te 1 sq cm	Low	High
Q4201	Matrion 1 sq cm	Low	High
Q4203	Derma-gide, 1 sq cm	High	High*
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High
Q4209	Surgraft per sq cm	Low	High
Q4210	Axolotl graf dualgraf sq cm	Low	Low
Q4211	Amnion bio or axobio sq cm	Low	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	Low	Low
Q4218	Surgicord per sq cm	Low	Low
Q4219	Surgigraft dual per sq cm	Low	High
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low

CY 2022 HCPCS Code	CY 2022 Short Descriptor	CY 2021 High/Low Cost Assignment	Proposed CY 2022 High/Low Cost Assignment
Q4222	Progenamatrix, per sq cm	Low	High
Q4226	Myown harv prep proc sq cm	High	High
Q4227	Amniocore per sq cm	Low	High
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	Low	Low
Q4232	Corplex, per sq cm	Low	High
Q4234	Xcellerate, per sq cm	High	High
Q4235	Amniorepair or altiply sq cm	Low	Low
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	Low	High
Q4238	Derm-maxx, per sq cm	Low	High
Q4239	Amnio-maxx or lite per sq cm	Low	High
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	Low	Low
Q4249	Amniply, per sq cm	Low	High
Q4250	AmnioAMP-MP per sq cm	Low	Low
Q4254	Novafix dl per sq cm	Low	Low
Q4255	Reguard, topical use per sq	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2022, but are assigned to the high cost group because they were assigned to the high cost group in CY 2021.

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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 a proposed estimate of pass-through spending in CY 2022 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 2022. 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 2021 or beginning in CY 2022. The sum of the proposed CY 2022 pass-through spending estimates for these two groups of device categories equaled the proposed total CY 2022 pass-through spending estimate for device categories with pass-through payment status. We based 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 methodology 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 proposed rule, we propose 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 2022, we also propose 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 2022 for this group of items is $462.4 million, as discussed below, because we propose that most non pass-through separately payable drugs and biologicals would be paid under the CY 2022 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs, which we propose would be paid at ASP minus 22.5 percent, and because we propose to pay for CY 2022 pass-through payment drugs and biologicals at ASP+6 percent, as we discuss in section V.A. of this CY 2022 OPPS/ASC proposed rule.

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 non pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, drugs and biologicals that function as supplies when used in a surgical procedure, drugs and biologicals used for anesthesia, and drugs and biologicals, as discussed in section V.B.1.c. of this CY 2022 OPPS/ASC proposed rule. We propose that all of these policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2022. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2022 is not $0, as discussed below. In section V.A.6. of this proposed rule, we discuss 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 propose 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 propose 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 2022. 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 2021 or beginning in CY 2022. The sum of the CY 2022 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2022 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending

For 2022, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2022, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2021 (85 FR 86068).

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 2022, there are 9 active categories for CY 2022. The active categories are described by HCPCS codes C2596, C1734, C1982, C1824, C1839, C1748, C1825, C1052, and C1062. Based on the information from the device manufacturers, we estimate that HCPCS code C2596 will cost $11.3 million in pass-through expenditures in CY 2022, HCPCS C1734 will cost $36.9 million in pass-through

expenditures in CY 2022, HCPCS code C1982 will cost $116.3 million in pass-through expenditures in CY 2022, HCPCS code C1824 will cost $46 million in pass-through expenditures in CY 2022, HCPCS code C1839 will cost $500,000 in pass-through expenditures in CY 2022, HCPCS code C1748 will cost $39.1 million in pass-through expenditures in CY 2022, HCPCS code C1825 will cost $3.5 million in pass-through expenditures in CY 2022, HCPCS code C1052 will cost $40 million in pass-through expenditures in CY 2022, and HCPCS code C1062 will cost $14.3 million in pass-through expenditures in CY 2022. Therefore, we propose an estimate for the first group of devices of $307.9 million.

In estimating our proposed CY 2022 pass-through spending for device categories in the second group, we included: Device categories that we assumed at the time of the development of this proposed rule will be newly eligible for pass-through payment in CY 2022; additional device categories that we estimated could be approved for pass-through status after the development of the proposed rule and before January 1, 2022; and contingent projections for new device categories established in the second through fourth quarters of CY 2022. For CY 2022, we propose 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. The proposed estimate of CY 2022 pass-through spending for this second group of device categories is $244.4 million.

To estimate proposed CY 2022 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 at least one quarter in CY 2022, we propose to use the CY 2019 Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2022 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 2022, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. Separately payable drugs are paid at a rate of ASP+6 percent with the exception of 340B-acquired drugs, for which we propose to pay ASP minus 22.5 percent. Therefore, the payment rate difference between the pass-through payment amount and the non pass-through payment amount is $462.4 million 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 2022 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, which we estimate for CY 2022 for the first group of policy-packaged drugs to be $0 since there are currently no policy-packaged drugs for which we have cost data that will be on pass-through in CY 2022.

To estimate proposed CY 2022 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 or recently became eligible for pass-through payment in CY 2022, 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, 2022 and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2022), we propose 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 2022 pass-through payment estimate. We also propose to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2022 pass-through payments for this second group of drugs, we calculate a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

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 2022 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2022 would be approximately $1,024.7 million (approximately $552.3 million for device categories and approximately $472.4 million for drugs and biologicals) which represents 1.24 percent of total projected OPPS payments for CY 2022 (approximately $83 billion). Therefore, we estimate that pass-through spending in CY 2022 will not amount to 2.0 percent of total projected OPPS CY 2022 program spending.

As discussed in section X.E. of this proposed rule, due to the effects of the COVID–19 PHE, we are proposing to generally use CY 2019 claims data instead of CY 2020 claims data in establishing the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in CY 2021 final rule OPPS ratesetting. If our proposal to use CY 2019 data, rather than CY 2020 data, to inform CY 2022 ratesetting, is finalized, we would effectively remove approximately one year of pass-through data collection time for ratesetting purposes. Therefore, for CY 2022, in section X.E. of this proposed rule, we are proposing to use our equitable adjustment authority under 1833(t)(2)(E) to provide up to four quarters of separate payment for 21 drugs and biologicals whose pass-through payment status will expire on March 31, 2022, June 30, 2022, or September 30, 2022 and six drugs and biologicals and one device category whose pass-through payment status will expire on December 31, 2021. This would ensure that we have a full year of claims data from CY 2021 to use for CY 2023 ratesetting and would allow us to avoid using CY 2020 data to set rates for these pass-through drugs, biologicals, and the device category for CY 2022.

We estimated the spending for the drugs, biologicals, and device category for which we are proposing to provide separate payment for the remainder of CY 2022 using our equitable adjustment authority. To estimate proposed CY 2022 spending for the one device pass-through category with pass-through status expiring on December 31, 2021, we also used the general methodology

described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778). For this device category, we calculate a proposed spending estimate of $3.5 million. To estimate proposed CY 2022 spending for the six drugs with pass-through status expiring on December 21, 2021 and the 18 drugs and three biologicals with pass-through status expiring on March 30, 2022, June 30, 2022, and September 30, 2022 we performed an analysis similar to the analysis for the first group of drugs and biologicals described earlier in this section where we estimated the pass-through payment amount as the difference between ASP+6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. For this group, we calculate a proposed spending estimate for CY 2022 of $61.5 million. We estimate that total spending for these 27 drugs and biologicals and one device category would be approximately $65 million for CY 2022. The drugs, biologicals, and device category for which we propose to provide separate payment for one to four quarters in CY 2022 are listed in table 33 below.

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TABLE 33:
DEVICE CATEGORY, DRUGS, AND BIOLOGICALS WITH EXPIRING PASS-THROUGH STATUS THAT WOULD RECEIVE SEPARATE PAYMENT FOR ONE TO FOUR QUARTERS IN CY 2022

HCPCS Code	Long Descriptor	Pass-Through Status Effective Date	Pass-Through Status Expiration End Date	Proposed Adjustment Equivalent to an Extension of Pass-through Status (number of quarters)
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads)	01/01/2019	12/31/2021	4
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	01/01/2019	12/31/2021	4
J0222	Injection, Patisiran, 0.1 mg	01/01/2019	12/31/2021	4
J0291	Injection, plazomicin, 5 mg	01/01/2019	12/31/2021	4
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	01/01/2019	12/31/2021	4
J2798	Injection, risperidone, (perseris), 0.5 mg	01/01/2019	12/31/2021	4
J9204	Injection, mogamulizumab-kpkc, 1 mg	01/01/2019	12/31/2021	4
J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	04/01/2019	03/31/2022	3
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	04/01/2019	03/31/2022	3
J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	01/01/2020	03/31/2022	3
J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	04/01/2019	03/31/2022	3
J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	04/01/2019	03/31/2022	3
J3245	Injection, tildrakizumab, 1 mg	04/01/2019	03/31/2022	3
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	04/01/2019	03/31/2022	3
J9119	Injection, cemiplimab-rwlc, 1 mg	04/01/2019	03/31/2022	3

J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	04/01/2019	03/31/2022	3
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	04/01/2019	03/31/2022	3
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	04/01/2019	03/31/2022	3
Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	04/01/2019	03/31/2022	3
C9047	Injection, caplacizumab-yhdp, 1 mg	07/01/2019	06/30/2022	2
J0121	Injection, omadacycline, 1 mg	07/01/2019	06/30/2022	2
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	07/01/2019	06/30/2022	2
J1303	Injection, ravulizumab-cwvz, 10 mg	07/01/2019	06/30/2022	2
J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	07/01/2019	06/30/2022	2
J9210	Injection, emapalumab-lzsg, 1 mg	07/01/2019	06/30/2022	2
J9269	Injection, tagraxofusp-erzs, 10 micrograms	07/01/2019	06/30/2022	2
J3111	Injection, romosozumab-aqqg, 1 mg	10/01/2019	09/30/2022	1
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	10/01/2019	09/30/2022	1

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VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2022, we propose 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 propose to continue our payment policy for critical care services for CY 2022. 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 this proposed rule, we are seeking 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 are continuing the clinic visit payment policy for CY 2022 and beyond. We will continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by excepted off-campus provider-based departments. The PFS-equivalent rate for CY 2022 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate). Under this policy, these departments will be paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in CY 2022) for the clinic visit service in CY 2022. We will continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of OPD services.

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. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional guidance regarding PHP.

In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule (73 FR 68688 through 68697). In 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 (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: Two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176) and instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, 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 (76 FR 74348 through 74352). 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. 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) and 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 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 2016, we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers and renumbered the PHP APCs. In 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 and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. 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).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352). We refer readers to section VIII.D. of this proposed rule for a discussion of the proposed updates and the applicability for CY 2021.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized our proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, 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.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID–19 PHE.

In the CY 2021 final rule (85 FR 86073 through 86080), we finalized a CMHC geometric mean per diem cost of $136.14 and a final hospital-based PHP geometric mean per diem cost of $253.76 using the most recent updated claims and cost data. In the CY 2021 proposed rule (85 FR 48901 through 48905), we had proposed, for CY 2021 and subsequent years, to use the CY 2021 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for CMHCs of $121.62 that was calculated for CY 2020 ratesetting (84 FR 61339 through 61344), as the basis for developing the CY 2021 CMHC APC per diem rate. We had also proposed, for CY 2021 and subsequent years, to use the CY 2021 hospital-based geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for hospital-based providers of $222.76 that was calculated for CY 2020 ratesetting (84 FR 61344 through 61345). We explained in the final rule that the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor,

therefore a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPPS/ASC final rule with comment period.

B. Proposed PHP APC Update for CY 2022

1. Proposed PHP APC Geometric Mean Per Diem Costs

In summary, for CY 2022 only, we propose to use the CY 2022 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for CMHCs of $136.14, which is the final CMHC geometric mean per diem cost calculated last year for CY 2021 ratesetting (85 FR 86080), as the basis for developing the CY 2022 CMHC APC per diem rate. We also propose, for CY 2022 only, to use the CY 2022 hospital-based geometric mean per diem cost calculated in accordance with our existing methodology, but with a cost floor equal to the per diem cost for hospital-based providers of $253.76 calculated last year for CY 2021 ratesetting (85 FR 86080). Following this methodology, we propose to use the cost floor value of $136.14 for CMHCs as the basis for developing the CY 2022 CMHC APC per diem rate, and to use the cost floor value of $253.76 as the basis for developing the CY 2021 hospital-based APC per diem rate. As discussed in section VIII.B.2 of this proposed rule, we propose to use the latest available CY 2019 claims and cost data from the CY 2021 rulemaking to determine CY 2022 geometric mean per diem costs in this proposed rule, and we propose that if the final CY 2022 cost for CMHCs or hospital-based PHPs is calculated to be above the proposed floor for that provider type, we would use the final calculated cost instead of the floor. The rationale behind this proposal is discussed in greater detail in sections VIII.B.2.a and VIII.B.2.b of this proposed rule.

Lastly, in accordance with our longstanding policy, we propose to continue to use CMHC APC 5853 (Partial Hospitalization (three or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)). These proposals are discussed in more detail below.

2. Development of the Proposed PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2022, we followed 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 calculate the PHP APCs' geometric mean per diem costs and 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 three 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 three or more services. In addition, for this CY 2022 proposed rulemaking, we used cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF). We discuss this proposed change in greater detail in section VIII.B.2.a of this OPPS/ASC proposed rule.

As discussed in section X.E of this OPPS/ASC proposed rule, we analyzed OPPS cost and claims information from CY 2019 and CY 2020 to better understand the effects of the COVID–19 PHE on outpatient services, including PHP, and to identify which data would be the best available for ratesetting. As discussed in that section, we observed a number of changes, likely as a result of the COVID–19 PHE, in the CY 2020 OPPS claims that we would ordinarily use for ratesetting, and this includes changes in the claims for partial hospitalization. For PHP services in particular, we identified that for hospital-based PHPs, the number of PHP days in our trimmed CY 2020 claims dataset was approximately 53 percent less than the number of PHP days in our trimmed CY 2019 claims dataset; and for CMHCs, the number of PHP days in our trimmed CY 2020 claims dataset was approximately 45 percent less than the number of PHP days in our trimmed CY 2019 claims dataset.

For this CY 2022 ratesetting, we are proposing to use CY 2019 claims and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking. We believe this is appropriate and necessary for PHP services, because of the substantial decrease in the number of PHP days in the CY 2020 claims dataset, which we would normally use for ratesetting. Furthermore, there was a substantial decrease in the number of PHP providers in the CY 2020 data. Our trimmed CY 2020 claims dataset contains cost and claim information from 35 fewer hospital-based PHP providers than are in the CY 2019 data. These significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims lead us to believe that CY 2020 data are not the best overall approximation of expected PHP services in CY 2022. We believe that CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, are a better approximation of expected CY 2022 PHP services. Therefore, as discussed in section X.E of this OPPS/ASC proposed rule, and consistent with what CMS is proposing to do for other APCs under the OPPS, we are proposing to use CY 2019 claims and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 CMHC and hospital-based PHP APC per diem costs.

The CMHC or hospital-based PHP APC per diem costs are the provider-type specific costs derived from the latest updated CY 2019 claims and cost data from the CY 2021 rulemaking. 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 geometric mean per diem costs, after applying the OPPS budget neutrality adjustments described in section XX of this proposed rule.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this CY 2022 OPPS/ASC proposed rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465). However, as discussed above, we propose to use CY 2019 claims data and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 CMHC PHP APC per diem cost.

For this CY 2022 proposed rule, we also used cost and charge information from HCRIS as the basis for determining the CMHC CCRs used to calculate the geometric mean per diem cost for CMHC APC 5853. Following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462), we calculated the CCR based on Medicare costs and charges. However, we note that CMHCs are now reporting their costs using the newer cost

reporting form, Form CMS 2088–17, which has different lines and columns than the ones described in the CY 2016 OPPS/ASC final rule for Form CMS 2088–92. Therefore, to calculate each CMHC's CCR for this proposed rulemaking, we divided costs from Worksheet C, Line 50, Column 5 by charges from Worksheet C, Line 50, Column 4.

As noted above, prior to this year's proposed rulemaking, our longstanding methodology for calculating CCRs for CMHCs has been to use the CCRs from the OPSF. As discussed in the CY 2004 OPPS/ASC final rule (68 FR 63468), a Program Memorandum was issued on January 17, 2003, which directed the fiscal intermediaries to recalculate hospital and CMHC cost-to-charge ratios and to update the cost-to-charge ratios on an ongoing basis in the OPSF, which was used as the basis for the CCRs used in calculating the geometric mean per diem costs for CMHCs. Subsequently, in the CY 2009 OPPS/ASC final rule (73 FR 68690), commenters addressed the fact that cost report information for CMHCs was not at that time included in HCRIS, and recommended that CMS base its calculations only in the cost report information that the agency can verify directly and not on data provided by the fiscal intermediary. CMS responded in the same OPPS/ASC final rule that it was working to include CMHC cost reports in the system, but that the CCRs from the OPSF continued to be the best available data for ratesetting. In the CY 2011 OPPS/ASC final rule (75 FR 71993 through 71994), commenters requested that CMHC cost report information be included in HCRIS, and CMS explained that CMHC cost reports would begin to be available in HCRIS starting in early 2011. Since that time, CMHC cost reports have become available in HCRIS. Because the data is now available and consistently populated based on the cost reports that CMHCs submit, we believe that using cost information from HCRIS would be more consistent with the methodology for calculating most other OPPS services, including hospital-based PHP services. Therefore, we are proposing for CY 2022 and future years to use HCRIS as the source for CMHC cost information used for calculating the geometric mean per diem cost for CMHC APC 5853.

Prior to calculating the proposed geometric mean per diem cost for CMHC APC 5853, we prepare 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. Before any trims or exclusions were applied, there were 40 CMHCs in the PHP claims data file. Under the ±2 standard deviation trim policy, we exclude 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. In applying this trim for CY 2022 ratesetting, one CMHC had geometric mean costs per day below the trim's lower limit of $32.84, and one had geometric mean costs per day above the trim's upper limit of $491.85. Therefore, we are excluding data for ratesetting from these 2 CMHCs because of the ±2 standard deviation trim.

In accordance with our PHP ratesetting methodology (80 FR 70465), 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 2022 proposed rule ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. We also exclude providers without any days containing 3 or more units of PHP-allowable services. One provider is excluded from ratesetting because it had no days containing 3 or more units of PHP-allowable services. In addition to our trims and data exclusions, before calculating 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 that is not available or any CMHC CCR greater than one to the statewide hospital CCR associated with the provider's urban/rural designation and their state location (80 FR 70463). For this CY 2022 OPPS/ASC proposed rule ratesetting, there are 3 CMHCs with CCRs greater than one, and 12 CMHCs with missing CCR information. Therefore, we are defaulting the CCRs for these 15 CMHCs for ratesetting to the applicable statewide hospital CCR for each CMHC based on its urban/rural designation and its state location.

In summary, these data preparation steps adjusted the CCR during our ratesetting process for 15 CMHCs having either a CCR greater than one or having no CCR. We are also excluding one CMHC because it had no days containing 3 or more services and 2 CMHCs for failing the ±2 standard deviation trim, resulting in the inclusion of 37 CMHCs. There were 564 CMHC claims removed during data preparation steps due to the ±2 standard deviation trim or because they either had no PHP allowable- codes or had zero payment days, leaving 10,370 CMHC claims in our CY 2022 proposed rule ratesetting modeling. After applying all of the previously listed 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), using the CMHC CCRs calculated based on the cost information from HCRIS as discussed in this OPPS/ASC proposed rule, to calculate the CMHC APC geometric mean per diem cost.[103] The calculated CY 2022 geometric mean per diem cost for all CMHCs for providing three or more services per day (CMHC APC 5853) is $130.41, a decrease from $136.14 calculated last year for CY 2021 ratesetting (85 FR 86080).

We considered whether a geometric mean per diem cost for CMHCs of $130.41 would be appropriate for calculating the CMHC APC 5853 per diem payment rate for CY 2022. As discussed above, we used the latest available CY 2019 claims and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 CMHC PHP APC per diem cost, because decreases that we observed in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims have led us to believe that the CY 2019 data, rather than the CY 2020 data, are the best overall approximation of expected PHP services in CY 2022. We considered what effect a decrease from the $136.14 calculated last year for the CY 2021 CMHC PHP APC might have on CMHCs

[103] 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 or was missing) 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 three or more services provided to be assigned to CMHC APC 5853. The final 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 three 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 final geometric mean per diem cost for each PHP APC by taking the *n*th root of the product of *n* numbers for days where three or more services were provided.

and Medicare beneficiaries. Recognizing the disruption that the ongoing COVID–19 PHE appears to be having on CMHCs' operations, we believe it is important for CMS to continue to support Medicare beneficiaries' access to critical PHP services during the COVID–19 PHE by helping maintain the stability of payments to PHP providers. We are concerned that a decrease in the geometric mean per diem cost for CMHC APC 5853 would result in a disruption to CMHC payments at a time when, despite the large decrease in the number of PHP days that we observed in our CY 2020 PHP claims data, the need for mental health services has increased.[104] Therefore, rather than proposing to calculate the CMHC APC 5853 payment rate based on the calculated geometric mean per diem cost of $130.41, we are instead proposing a cost floor to stabilize the geometric mean per diem costs finalized in the prior year, CY 2021. The final CY 2021 geometric mean per diem cost for CMHC APC 5853, which was calculated for the CY 2021 OPPS/ASC final rule based on CY 2019 claims, is $136.14, which we are proposing as the cost floor for CY 2022. Therefore, because the calculated geometric mean per diem cost for CMHC APC 5853 is below the cost floor, we are proposing to calculate the CY 2022 CMHC APC 5853 payment rate based on the cost floor of $136.14. We also propose that if the final CY 2022 geometric mean per diem cost is calculated to be higher than $136.14, then we would use the calculated geometric mean per diem cost.

As discussed earlier in this section, 3 CMHCs in our dataset had CCRs greater than 1, and 12 CMHCs had missing CCRs. We want to remind readers that our PHP ratesetting methodology depends heavily on provider-reported costs. We strongly encourage CMHCs to review cost reporting instructions to be sure they are reporting their costs correctly. These instructions are available in chapter 45 of the Provider Reimbursement Manual (PRM), Part 2, available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals*. We want to reiterate that it is a requirement for CMHCs, unless they are approved as a low-utilization or no-utilization provider in accordance with PRM–1, chapter 1, section 110 (42 CFR 413.24(g) and (h)), to file full cost reports, to help us capture accurate CMHC costs in rate setting. We furthermore encourage those CMHCs that do not file full cost reports to consider doing so.

We continue to recognize that because the CMHC ratesetting dataset is small (n=37), changes in costs from a small number of providers can influence the overall geometric mean per diem cost calculation. We are considering approaches to address cost fluctuations in future years, however, we are not proposing a methodology at this time.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2022 proposed rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for hospital-based PHP providers, which is similar to that used for CMHCs. However, as discussed above, we propose to use CY 2019 claims data and the cost information from prior to the COVID–19 PHE, that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking, for calculating the CY 2022 hospital-based PHP APC per diem cost. The CY 2019 PHP claims included data for 449 hospital-based PHP providers for our calculations in this CY 2022 OPPS/ASC proposed rule.

Consistent with our policies, as stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), we prepared the data by applying trims and data exclusions. We applied a trim on hospital service days for hospital-based PHP providers with a CCR greater than 5 at the cost center level. To be clear, 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 the CCR greater than 5 trim removed affected service days from one hospital-based PHP provider from our proposed ratesetting. However, 100 percent of the service days for this hospital-based PHP provider had at least one service associated with a CCR greater than 5, so the trim removed this provider entirely from our proposed ratesetting. In addition, 68 hospital-based PHPs were removed for having no days with PHP payment. Two hospital-based PHPs were removed because none of their days included PHP-allowable HCPCS codes. No hospital-based PHPs were removed for missing wage index data, and a single hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day. (We refer readers to the OPPS Claims Accounting Document, available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1717-P-2020-OPPS-Claims-Accounting.pdf*.

Overall, we removed 72 hospital-based PHP providers (1 with all service days having a CCR greater than 5) + (68 with no PHP payment) + (2 with no PHP-allowable HCPCS codes) + (1 provider with geometric mean costs per day outside the ± 3 SD limits)], resulting in 377 (449 total − 72 excluded) hospital-based PHP providers in the data used for calculating ratesetting.

After completing these data preparation steps, we calculated the CY 2022 geometric mean per diem cost for hospital-based PHP APC 5863 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).[105] The calculated CY 2022 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide three or more services per service day (hospital-based PHP APC 5863) is $253.08, which is a very slight decrease from $253.76 calculated last year for CY 2021 ratesetting (85 FR 86080).

As we discussed above, we observed a number of changes, likely as a result of the COVID–19 PHE, in the CY 2020 OPPS claims that we would ordinarily use for ratesetting, and this includes changes in the claims for partial hospitalization. We considered what effect this very slight decrease from the $253.76 calculated last year for the CY 2021 CMHC PHP APC might have on CMHCs and Medicare beneficiaries. In general, a decrease of this magnitude would not be unexpected due to normal variation in cost and claims data. However, recognizing the disruption

[104] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm.*

[105] 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; in CY 2020 and subsequent years, that CCR is determined by using the PHP-only 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 three or more services provided to be assigned to hospital-based PHP APC 5863. The final 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 three 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 final geometric mean per diem cost for hospital-based PHP APC 5863.

that the ongoing COVID–19 PHE appears to be having on the operations of hospital-based PHPs, we believe it is important for CMS to continue to support Medicare beneficiaries' access to critical PHP services during the COVID–19 PHE by helping to maintain the stability of payments to PHP providers. While the decrease in the geometric mean per diem cost for hospital-based PHP APC 5863 would be very slight based on the CY 2019 claims and cost data used for this CY 2022 OPPS/ASC proposed rule, we continue to believe, as we have stated before in recent years, that access is better supported when geometric mean per diem costs do not fluctuate greatly. The proposed cost floor would protect access to PHP services at hospital-based PHPs if the final CY 2022 calculated hospital-based PHP APC geometric mean per diem cost is significantly less. We are concerned that such a decrease may result in a disruption to hospital-based PHP payments at a time when, as discussed earlier in section VII.B.2.a of this OPPS/ASC proposed rule, the need for mental health services has increased. Therefore, we are proposing to calculate the hospital-based PHP APC 5863 payment rate based on a cost floor to maintain the geometric mean per diem costs finalized in the prior year, CY 2021. The final CY 2021 geometric mean per diem cost for hospital-based PHP APC 5863, which was calculated for the CY 2021 OPPS/ASC final rule based on CY 2019 claims, is $253.76, which we are proposing as the cost floor for CY 2022. Therefore, because the calculated geometric mean per diem cost for hospital-based PHP APC 5863 is below the cost floor, we are proposing to calculate the CY 2022 hospital-based PHP APC 5863 payment rate based on the cost floor of $253.76. We also propose that if the final CY 2022 geometric mean per diem cost is calculated to be higher than $253.76, then we would use the calculated geometric mean per diem cost.

We continue to recognize, as we have noted in past years, that changes in costs from a small number of providers can influence the overall geometric mean per diem cost calculation. We are considering approaches to address cost fluctuations in future years, however we are not proposing a methodology at this time.

These proposed CY 2022 PHP geometric mean per diem costs are shown in Table 34 and are used to derive the proposed CY 2022 PHP APC per diem rates for CMHCs and hospital-based PHPs. The proposed CY 2022 PHP APC per diem rates are included in Addendum A to this proposed rule (which is available on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).[106]

TABLE 34: CY 2022 PHP APC Geometric Mean Per Diem Costs

CY 2022 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (three or more services per day) for CMHCs	$136.14
5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$253.76

C. Proposed Outlier Policy for CMHCs

For 2022, we propose 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. We refer readers to section II.G.1 of this CY 2022 OPPS/ASC proposed rule 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

[106] As discussed in section XX. of this CY 2022 OPPS/ASC proposed rule, 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 proposed rule for more information on scaling the weights, and for details on the final steps of the process that leads to final 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*.

59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082).

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. To calculate the CMHC outlier percentage, we follow three steps:

- Step 1: We multiply 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 estimate 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 proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.C.3. of this proposed rule, 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 proposed rule, 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 sum 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 determine 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).

We propose to continue to calculate the CMHC outlier percentage according to previously established policies, and we do not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2022. Therefore, based on our CY 2022 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2022, excluding outlier payments. We propose 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.

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). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in CY 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))]. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997), CY 2020 OPPS/ASC final rule with comment period (84 FR 61351) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 through 86083). For CY 2022, we propose 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 2022, 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))].

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. We 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.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

We propose to continue these policies for partial hospitalization services provided through PHPs for CY 2022. 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).

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, it 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. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years. In this proposed rule, we are not proposing any changes to this policy.

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). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083). We propose to continue this policy for CY 2022.

IX. Proposed Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPPS, the inpatient only (IPO) list identifies services for which Medicare will only make payment when the services are furnished in the inpatient hospital 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 (70 FR 68695). The IPO list was created based on the premise (rooted in the practice of medicine at that time), that Medicare should not pay for procedures furnished as outpatient services that are performed on an inpatient basis virtually all of the time for the Medicare population, either because of the invasive nature of the procedures, the need for postoperative care, or the underlying physical condition of the patient who would require such surgery, because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules (63 FR 47571). Services included on the IPO list were those determined to require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care (65 FR 67826). There are some services designated as inpatient only that, given their clinical intensity, would not be expected to be performed in the outpatient setting. For example, we have traditionally considered certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, to require inpatient care (65 FR 18456). Designation of a service as inpatient-only does not preclude the service from being furnished in a hospital outpatient setting, but means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the outpatient setting (65 FR 18443). Conversely, the absence of a procedure from the list should not be interpreted as identifying those procedures as appropriately performed only in the outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested stakeholders, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed from the list. Stakeholders were encouraged to request reviews for a particular code or group of codes; and we have asked that their requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals—including but not limited to—operative reports of actual cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data (67 FR 66740).

Prior to CY 2021, we traditionally used five criteria to determine whether a procedure should be removed from the IPO list (65 FR 18455). As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we assessed whether a procedure or service met these criteria to determine whether or not it 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 have explained that a procedure is not required to meet all of the established criteria to be removed from the IPO list. The criteria for assessing procedures for removal from the IPO list prior to CY 2021 are the following:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that we have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

In the past, we have requested that stakeholders submit corresponding evidence in support of their claims that a code or group of codes met the longstanding criteria for removal from the IPO list and was safe to perform on the Medicare population in the outpatient setting—including, but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols. Our medical advisors thoroughly reviewed all information submitted within the context of the established criteria and if, following this review, we determined that there was sufficient evidence to confirm that the code could be safely

and appropriately performed on an outpatient basis, we assigned the services to an APC and included it as a payable procedure under OPPS (67 FR 66740).

We stated in prior rulemaking that, over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide for payment for them under the OPPS (65 FR 18443). Prior to CY 2021, changes to the IPO list have been gradual. Further, CMS has at times had to reclassify codes as inpatient only services with the emergence of new information.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our historic policies for identifying services that are typically provided only in an inpatient setting and, therefore, that will not be paid by Medicare under the OPPS, as well as the criteria we have used to review the IPO list to determine whether or not any services should be removed from the list.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088), we significantly adjusted our approach to the IPO list. As we stated in that final rule, we no longer saw the need for CMS to restrict payment for certain procedures by maintaining the IPO list to identify services that require inpatient care. In that final rule, we acknowledged the seriousness of the concerns regarding patient safety and quality of care that various stakeholders expressed regarding removing procedures from the IPO list or eliminating the IPO list altogether. But we stated that we believed that the developments in surgical technique and technological advances in the practice of medicine, as well as various safeguards, including, but not limited to, physician clinical judgment, state and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, CMS quality and monitoring initiatives and programs and other CMS initiatives would continue to ensure that procedures removed from the IPO list and provided in the outpatient setting could be performed safely on appropriately selected beneficiaries. We also stated that given our increasing ability to measure the safety of procedures performed in the outpatient setting and to monitor the quality of care, in addition to the other safeguards detailed above, we believed that quality of care was unlikely to be affected by the elimination of the IPO list. We noted that we do not require services that are not included on the IPO list to be performed solely in the outpatient setting and that services that were previously identified as inpatient only can continue to be performed in the inpatient setting. We emphasized that physicians should use their clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary, subject to the general coverage rules requiring that any procedure be reasonable and necessary. We also stated that the elimination of the IPO list would ensure maximum availability of services to beneficiaries in the outpatient setting. Finally, we stressed that as medical practice continues to develop, we believed that the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services.

Accordingly, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86084 through 86088), we finalized, with modification, our proposal to eliminate the IPO list over the course of three years (85 FR 86093). We revised our regulation at § 419.22(n) to state that, effective on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a three-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes from the list beginning in CY 2021 and, because we proposed to eliminate the IPO list entirely, the removed procedures were not assessed against our longstanding criteria for removal (85 FR 86094).

B. Proposed Changes to the Inpatient Only (IPO) List

In this proposed rule, for CY 2022, we propose to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list, we propose to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022. In accordance with this proposal, we propose to amend the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a three-year transition. We also propose to codify the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation in a new § 419.23.

1. Stakeholder Feedback on Eliminating the IPO List

We received a significant number of stakeholder comments throughout the CY 2021 rulemaking cycle and following issuance of the final rule about eliminating the IPO list. Many commenters, including hospital associations and hospital systems, professional associations, and medical specialty societies, vociferously opposed eliminating the IPO list. These commenters primarily cited patient safety concerns, stating that the IPO list serves as an important programmatic safeguard and maintains a common standard of medical judgment in the Medicare program. Stakeholders stated that they support maintaining the IPO list and consider it an important tool to indicate which services may be appropriate to furnish in the outpatient setting (by virtue of the procedures not being on the IPO list) and to ensure that Medicare beneficiaries receive quality care. Commenters argued that many of the procedures that we designated as ''inpatient only'' are currently performed appropriately and safely only in the inpatient setting, and therefore, should remain on the IPO list. Additionally, commenters opposed eliminating the IPO list and stated that high-risk, invasive procedures that require post-operative monitoring would not be safe to perform on Medicare beneficiaries in an outpatient setting. While some commenters acknowledged that eliminating the IPO list would provide increased beneficiary access to care, these commenters were concerned that the increased access would be to lower quality care.

Many commenters who were opposed to eliminating the IPO list stated that CMS should retain the current methodology for evaluating and removing procedures from the IPO list through rulemaking. Alternatively, several commenters requested that instead of eliminating the IPO list, CMS should instead maintain the list specifically for a smaller number of procedures that are complex, surgically invasive, and that commenters believe should never be performed in the outpatient setting. The commenters suggested that these procedures be considered appropriate for inpatient

hospital admission and payment under Medicare Part A regardless of the expected length of stay.

While some commenters believed that eliminating the IPO list would remove regulatory barriers and provide patients with more choices for where to receive affordable care, other commenters expressed concerns that eliminating the IPO list would cause administrative and financial burdens for beneficiaries, hospitals, and payers given the number of transitioning codes and the speed with which they would be removed from the list.

A minority of commenters (including providers and trade associations) supported CMS eliminating the IPO list and stated that deference should be given to physicians' judgment on site-of-service decisions. These commenters stated that there is no clinical difference between a surgery performed on an inpatient versus an outpatient, and that eliminating the IPO list would create more flexibility for physicians and beneficiaries. The commenters also believed that eliminating the IPO list could potentially decrease overall healthcare costs and improve clinical outcomes for patients.

Commenters who supported delaying the elimination of the IPO list suggested various timeframes that ranged from three years to seven years. Several hospital associations recommended we delay eliminating the IPO list until we address patient safety concerns and provide national guidelines to identify patients who are appropriate candidates for care in the inpatient hospital versus outpatient hospital settings. During the 2021 rulemaking cycle, a few stakeholders suggested that we remove the proposed musculoskeletal services from the IPO list and then monitor the transition of those services to the outpatient hospital setting and the effect on beneficiary outcomes for a period of time before removing any additional services.

Following the CY 2021 OPPS/ASC final rule with comment period, stakeholders continued to express concerns regarding the pace at which the IPO list would be eliminated, the perceived lack of transparency in determining the order of removal of procedures over the course of the elimination process, and what stakeholders believed were insufficient details concerning rate setting for procedures for which payment would be made when furnished in the HOPD setting, as well as the accuracy of those rates for the HOPD setting. We have received stakeholder requests to reconsider the elimination of the IPO list, to reevaluate procedures removed from the IPO list due to safety and quality concerns, and to, at a minimum, extend the timeframe for eliminating the list.

2. Proposal To Halt the Elimination of the IPO List in CY 2022

After further consideration of the policy we adopted in last year's final rule with comment period and the concerns stakeholders have raised since the final rule was issued, we believe that we should halt the elimination of the IPO list to ensure that any service removed from the IPO list is evaluated against the previous longstanding criteria for removal from the IPO list before it is removed. We believe assessing whether a procedure or service meets the criteria for removal would allow for a more gradual removal of services from the IPO list—which would also allow stakeholders more time to evaluate the safety of the service in the HOPD and to prepare to safely furnish the services migrating off of the IPO list, if they so choose.

After further consideration, we continue to believe that the inpatient only list is a valuable tool for ensuring that the OPPS only pays for services that can safely be performed in the hospital outpatient setting, and we have reconsidered eliminating the inpatient only list at this time. We believe that there are many surgical procedures that cannot be safely performed on a typical Medicare beneficiary in the hospital outpatient setting, and therefore, it would be inappropriate for us to assign them separately payable status indicators and establish payment rates in the OPPS (78 FR 75055). We recognize that while physicians are able to make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries, that is, the typical Medicare beneficiary. While we want to afford physicians and hospitals the maximum flexibility in choosing the most clinically appropriate site of service for the procedure, as long as the characteristics of the procedure are consistent with the criteria listed above, we believe that the IPO list is a necessary safeguard that considers the broader Medicare population.

In the CY 2021 OPPS/ASC final rule with comment period, we recognized that stakeholders may need time to adjust to the removal of procedures from the list, especially given the significant number of services removed beginning in CY 2021 (85 FR 86085 and 86092). We recognized that providers may need time to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or the OPPS (85 FR 86086). We also acknowledged that it will take time for clinical staff and providers to gain experience furnishing these services to the appropriate Medicare beneficiaries in the HOPD, and to develop comprehensive patient selection criteria and other protocols to identify whether a beneficiary can safely have these procedures performed in the outpatient setting (85 FR 86088).

Separately, we also acknowledged the numerous challenges that providers are facing due to the COVID–19 PHE (85 FR 86089). After further experience with the PHE and its impact on provider and beneficiary behavior, we recognize that the COVID–19 PHE has likely reduced providers' ability to prepare to furnish these services in the outpatient setting in the manner they would absent the PHE. We recognize that the COVID–19 PHE may have negatively impacted the time and resources that providers have to adapt to the removal of these procedures from the IPO list—making it more difficult for providers to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or the OPPS. We also recognize that the COVID–19 PHE has negatively impacted clinical staff and providers' opportunity to develop the comprehensive patient selection criteria and other protocols necessary to identify whether a Medicare beneficiary could safely have these procedures performed in the outpatient setting while guaranteeing them appropriate quality of care.

After further consideration and review of the additional feedback from stakeholders, we recognize that the timeframe we finalized in the CY 2021 final rule with comment period for eliminating the IPO list did not, and would not, give us a sufficient opportunity to carefully assess whether a procedure should be payable in the HOPD setting, with considerations to beneficiary safety and medical advancements. We also recognize that the unprecedented removal of the 298 codes from the IPO list transpired quickly. Given the significant policy shift and work required to operationalize the elimination of the IPO list, we recognize that more time is required to separately evaluate and consider the inpatient only classification of each service and its potential APC assignment. In addition, we believe that we should continue to use the longstanding criteria for removing services from the IPO list to evaluate each service before proposing

to remove it from the list, and, as noted above, we propose to codify these criteria in the regulation in a new § 419.23.

CMS still believes that as medical practice continues to develop, the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services. While we recognize that there are services currently classified as inpatient only that may be appropriate in the outpatient setting for some Medicare beneficiaries, CMS continues to strive to balance the goals of increasing physician and patient choice of setting of care with considerations to patient safety for all Medicare beneficiaries. We must also consider the timing with which we remove services from the IPO list and the availability of evidence that may support the removal of those services. We believe that with additional time stakeholders can provide supportive evidence to aid in the evaluations of each individual procedure's assignment to the IPO list, and where appropriate the APC assignment and corresponding payment for any codes as well, including but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols.

An initial review of 2021 billing data through May 21, 2021, supports our proposal to halt the elimination of the list, revealing that 131 of the 298 codes removed from the IPO list in last year's final rule appeared on either zero or one OPPS claims and 269 of the 298 codes appeared on fewer than 100 claims. These data indicate that fewer than 3 percent of the services removed from the IPO list in 2021 have seen notable volume in the outpatient setting following their removal from the IPO list. For perspective, we also note that even before we removed these codes from the IPO list, it was not uncommon to see at least some volume for these codes in the claims data. In CY 2020, when these codes were still not payable under the OPPS, 188 of the codes had at least one outpatient claim and 18 codes had greater than 100 claims, for reasons undetermined. As a result, it is likely that not all of the reported claims represent services provided in the outpatient setting due to these services being removed from the IPO list in CY 2021.

We propose to halt the elimination of the IPO list in order to allow for greater consideration of the impact removing services from the list has on beneficiary safety and to allow providers impacted by the COVID–19 PHE additional time to prepare to furnish appropriate services safely and efficiently before continuing to remove large numbers of services from the list. Below we solicit comments on the potential future elimination of the IPO list and what commenters believe the effects of that elimination would be. We also solicit comment on if CMS should maintain the IPO list but continue to systematically scale back the list by looking at groups of services that can safely and effectively be performed in the outpatient setting. Specifically, CMS is requesting comments on whether CMS should maintain the longer-term objective of eliminating the IPO list and if so, suggestions for a reasonable timeline for the elimination and what method should be employed to evaluate procedure removal. We request that commenters submit evidence on what effect, if any, they believe eliminating or scaling back the IPO list will have on beneficiary quality of care and what effect, if any, would the elimination or scaling back of the IPO list have on provider behavior, incentives, or innovation. We are also interested in stakeholders' viewpoints on the clinical, financial, and administrative impact of removing services from the IPO list. Additionally, we are interested in stakeholders' suggestions for refining the approach to inpatient only code evaluation to keep pace with advances in technology and surgical techniques that allow for more services to appropriately take place in the outpatient setting if we were to retain the IPO list.

We reiterate that the removal of a particular procedure from the IPO list does not require that all beneficiaries be treated in the hospital outpatient setting, but we are cognizant that it does require the physician and clinical care team to exercise complex medical judgment to determine the appropriate setting of care, in accordance with the two-midnight rule guidance. The services that we are proposing to maintain or add back to the IPO list reflect those services that we believe may pose increased safety risk to the typical Medicare beneficiary. However, we recognize that there may be a subset of Medicare beneficiaries who, on a case by case basis, may nonetheless be appropriate to treat in the outpatient setting; and we seek comment below on whether any services that were removed in CY 2021, but are being proposed to be added back to the IPO for CY 2022, should in fact, remain off the IPO list.

3. Proposal To Return Procedures Removed in CY 2021 to the IPO List for CY 2022

CMS continues to believe that physicians must use their clinical knowledge and judgment, together with consideration of the beneficiary's needs, to determine the appropriate site of service, but we recognize that the broad removal of services from the IPO list in CY 2021 did not assess whether procedures proposed for removal met the longstanding removal criteria that we have historically used in consideration of the typical Medicare beneficiary. We also recognize that given the clinical intensity of some of the services removed from the IPO list (which include, for example, amputations), the 298 codes that were removed from the list included services that clinically would not be expected to be performed in the outpatient setting and would be unlikely to meet the criteria. As discussed previously, to ensure beneficiary safety, we have historically used longstanding criteria to determine if a procedure should be removed from the IPO list, but the removed procedures were not assessed against these criteria as part of the broad removal of services from the IPO list in CY 2021 because we proposed to eliminate the IPO list entirely. After further consideration, we believe it is important to continue to assess whether services individually meet any of the criteria for removal from the IPO list before being removed. Further, CMS recognizes that the impact of the COVID–19 PHE on providers' ability to safely and comprehensively prepare to furnish these services in the outpatient setting may be greater than previously anticipated. After a clinical review and an evaluation using the five longstanding criteria for removing services from the IPO list discussed earlier in Section IX(A) we now believe that the services removed from the IPO list in CY 2021 do not currently meet our longstanding removal criteria and we propose to add them back to the IPO list for CY 2022.

As discussed earlier in Section IX(A), we typically evaluate whether a service should be removed from the IPO list using five criteria and, while a service does not need to meet all of the criteria to be removed from the IPO list, it should meet at least one criterion and the case for removing the service from the IPO list is strengthened with the more criteria the service meets. For CY 2021, in light of our proposal to eliminate the IPO list over a three-year transition, we proposed that musculoskeletal services would be the

first group of services removed from the IPO list. We stated that we proposed to remove this group of services first for several reasons. In recent years, due to new technologies and advances in surgical care protocols, expedited rehabilitation protocols, and significant enhancements in postoperative processes, we have removed TKA and THA, which are both musculoskeletal services, from the IPO list. During the process of proposing and finalizing removing TKA and THA from the IPO list, stakeholders have continuously requested that CMS remove other musculoskeletal services from the IPO list as well, citing shortened length of stay times, advancements in technologies and surgical techniques, and improved postoperative processes. Additionally, we noted that, more often than not, stakeholders historically requested that we remove musculoskeletal services from the IPO list more than other types of services. We also recognized that there is already a set of comprehensive APCs for musculoskeletal services for payment under the OPPS, which facilitates payment for these services and further supported their removal for CY 2021. Specifically, because we have previously removed codes from the IPO list that are similar clinically and in terms of resource cost and assigned them to these comprehensive APCs, we explained that these APCs generally describe appropriate ranges for the musculoskeletal codes removed in CY 2021, which we believed allowed for appropriate payment. We also proposed to remove additional related services that were recommended for removal by stakeholders during the annual HOP panel meeting.

As stated above, because these services were being removed from the IPO list as the first phase of the elimination of the list, we did not evaluate each of these services against the longstanding criteria for removing a service from the IPO list. While a number of commenters supported the removal of the 298 services, the vast majority of commenters were opposed to removing the services and shared concerns regarding their inability to properly review the clinical nature of this large number of procedures and to provide comprehensive feedback on their removal from the list. Some commenters were able to review the individual services and requested that specific CPT codes remain payable in the inpatient setting only, including CPT codes 27280 (Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed) and 22857 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar) due to concerns about the safety of these procedures if they are performed in the outpatient setting.

As previously stated in the CY 2021 final rule (85 FR 86087), an overwhelming number of stakeholders supported the previously established methodology for identifying appropriate changes to the IPO list. CMS received numerous requests to continue to use the established criteria to review and analyze services proposed for removal as opposed to removing large numbers of services in groups or categories. Commenters noted that they preferred the historical process for assessing services for removal from the IPO list using the five criteria, as they believed this process was more manageable for patients, providers, and other like stakeholders, allowing them to provide meaningful input on a procedure-by-procedure basis. Because we are proposing to halt elimination of the IPO list, we also believe it is appropriate to continue to evaluate services that we propose for removal against the longstanding criteria, and include with our proposals an in depth analysis of whether most outpatient departments are equipped to provide the services to the Medicare population; whether the simplest procedure described by the code may be performed in most outpatient departments; whether the procedure is related to codes that we have already removed from the IPO list; our determination of whether the procedure is being performed in numerous hospitals on an outpatient basis; and our determination of whether the procedure can be appropriately and safely performed in an ASC, is on the list of approved ASC procedures, or has been proposed by us for addition to the ASC list. Historically, we have included discussions of the individual codes proposed for removal in the proposed rule and stakeholders have had the opportunity to comment in kind with evidence in support of or opposition to the service's assignment to the IPO list, and we believe it is appropriate to continue to do so.

In light of ongoing stakeholder feedback, we have now, for CY 2022, reviewed each of the procedures removed from the IPO list in CY 2021 to determine whether they individually meet the longstanding criteria for removal from the list. Our review considered the clinical intensity and characteristics of the service, the underlying condition of the beneficiary who would require the service, peer-reviewed medical literature, case reports, clinical criteria sets, and utilization data. This review determined that none of the services removed in CY 2021 have sufficient supporting evidence that the service can be safely performed on the Medicare population in the outpatient setting, that most outpatient departments are equipped to provide the services to the Medicare population, or that the services are being performed safely on an outpatient basis. For a large number of the removed services, we did not find vignettes, claims or utilization data, or literature to support their removal under our longstanding criteria. For the few services that did have some data supporting their removal from the list, we found the data to be either incomplete or to be countered by conflicting data. For example, a few services, including CPT code 21627 (sternal debridement), showed increasing migration to the outpatient setting, but we could not locate supportive medical literature case studies, or outcomes data to support that the services are safe for the Medicare population in the outpatient setting. Some services, such as CPT code 22558 (Lumbar spine fusion) and CPT code 23472 (reconstruct shoulder joint), show increasing outpatient claims data, but have high length of stay times and extensive post-operative care needs that indicate these services may not be appropriate for the Medicare population in the outpatient setting. Other services, such as CPT code 22846 (Anterior instrumentation; 4 to 7 vertebral segments), lack medical literature or case studies, lack supportive claims data, and have conflicting stakeholder feedback for the safety of the service in the outpatient setting. We were unable to find literature and data for services that included outcomes specific to the Medicare population, particularly in the outpatient setting.

Given that our review of each of the services removed from the list in CY 2021 using the five criteria mentioned in Section IX(A) did not find sufficient evidence that any of these services would be safe to perform on the Medicare population in the outpatient setting, we do not believe it would be appropriate for Medicare to pay for these services when performed in an outpatient setting. In particular, we found that the simplest procedures described by the codes for these services cannot be furnished safely in most outpatient departments, most outpatient departments are not equipped to

provide these services to the Medicare population, and the procedures are not being performed in numerous hospitals on an outpatient basis. We also do not believe the services can be appropriately and safely furnished in an ASC.

As a result of this review, we are proposing to return all of the procedures removed in last year's final rule to the IPO list for CY 2022 because we do not believe they meet the previously established criteria for removal from the IPO list. Therefore, after further clinical review and additional consideration of safety and quality of care concerns for the group of services removed from the IPO list in the CY 2021 final rule, for CY 2022 we are proposing to return these 298 services to the IPO list, as shown in Table 35 below. The complete list of codes describing services that we propose to designate as inpatient-only services beginning in CY 2022 is included as Addendum E to this CY 2022 OPPS/ASC proposed rule, which is available via the internet on the CMS website.

We solicit public comment on whether there are services that were removed from the IPO list in CY 2021 that stakeholders believe do meet the longstanding criteria for removing services from the IPO list and should continue to be payable in the outpatient setting in CY 2022. If so, we request that commenters submit corresponding evidence—including, but not limited to, case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols—that the service meets the longstanding criteria for removal from the IPO list and is safe to perform on the average Medicare population in the outpatient setting.

As mentioned above, the services that we are proposing to add back to the IPO list reflect those services that we believe may pose increased safety risk to the typical Medicare beneficiary. However, we recognize that there may be a subset of Medicare beneficiaries who, on a case by case basis, may nonetheless be appropriate to treat in the outpatient setting and we seek comment below on whether any services that were removed in CY 2021, but are being proposed to be added back to the IPO for CY 2022, should in fact, remain off the IPO list.

Table 35 below contains the proposed additions to the IPO list for CY 2022.

BILLING CODE 4120–01–P

TABLE 35.—PROPOSED ADDITIONS TO THE INPATIENT ONLY (IPO) LIST FOR CY 2022

2022 CPT Code	CY 2022 Long Descriptor	CY 2021 APC Assignment	CY 2021 Status Indicator
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N/A	N
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N/A	N
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (list separately in addition to code for primary procedure)	N/A	N
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar	N/A	N

	(list separately in addition to code for primary procedure)		
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	N/A	N
0202T	Posterior vertebral joint(s) arthroplasty (for example, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	5115	J1
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	5115	J1
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	5115	J1
20661	Application of halo, including removal; cranial	5113	Q1
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (for example, pediatric patients, hydrocephalus, osteogenesis imperfecta)	5113	Q1
20802	Replantation, arm (includes surgical neck of humerus through elbow joint), complete amputation	5116	J1
20805	Replantation, forearm (includes radius and ulna to radial carpal joint), complete amputation	5116	J1
20808	Replantation, hand (includes hand through metacarpophalangeal joints), complete amputation	5116	J1
20816	Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	5114	J1
20824	Replantation, thumb (includes carpometacarpal joint to mp joint), complete amputation	5114	J1
20827	Replantation, thumb (includes distal tip to mp joint), complete amputation	5114	J1
20838	Replantation, foot, complete amputation	5116	J1
20955	Bone graft with microvascular anastomosis; fibula	5114	J1
20956	Bone graft with microvascular anastomosis; iliac crest	5114	J1
20957	Bone graft with microvascular anastomosis; metatarsal	5114	J1
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	5114	J1
20969	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	5114	J1
20970	Free osteocutaneous flap with microvascular anastomosis; iliac crest	5114	J1
21045	Excision of malignant tumor of mandible; radical resection	5165	J1

21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (for example, for long face syndrome), without bone graft	5165	J1
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	5165	J1
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	5165	J1
21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	5165	J1
21146	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	5165	J1
21147	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	5165	J1
21151	Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)	5165	J1
21154	Reconstruction of midface bones with bone graft Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I	5165	J1
21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I	5165	J1
21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I	5165	J1
21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I	5165	J1
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	5165	J1
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	5165	J1
21182	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm	5165	J1
21183	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes	5165	J1

	obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm		
21184	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	5165	J1
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)	5165	J1
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	5165	J1
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	5165	J1
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (for example, for hemifacial microsomia)	5165	J1
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	5165	J1
21268	Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach	5165	J1
21343	Open treatment of depressed frontal sinus fracture	5165	J1
21344	Open treatment of complicated (for example, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	5165	J1
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	5165	J1
21348	Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)	5165	J1
21366	Open treatment of complicated (for example, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	5165	J1
21422	Open treatment of palatal or maxillary fracture (lefort i type);	5165	J1
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	5165	J1
21431	Closed treatment of craniofacial separation (lefort iii type) using interdental wire fixation of denture or splint	5165	J1
21432	Open treatment of craniofacial separation (lefort iii type); with wiring and/or internal fixation	5165	J1
21433	Open treatment of craniofacial separation (lefort iii type); complicated (for example, comminuted or	5165	J1

	involving cranial nerve foramina), multiple surgical approaches		
21435	Open treatment of craniofacial separation (lefort iii type); complicated, utilizing internal and/or external fixation techniques (for example, head cap, halo device, and/or intermaxillary fixation)	5165	J1
21436	Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	5165	J1
21510	Incision, deep, with opening of bone cortex (for example, for osteomyelitis or bone abscess), thorax	5114	J1
21602	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	5114	J1
21603	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	5114	J1
21615	Excision first and/or cervical rib;	5114	J1
21616	Excision first and/or cervical rib; with sympathectomy	5114	J1
21620	Ostectomy of sternum, partial	5114	J1
21627	Sternal debridement	5114	J1
21630	Radical resection of sternum;	5114	J1
21632	Radical resection of sternum; with mediastinal lymphadenectomy	5114	J1
21705	Division of scalenus anticus; with resection of cervical rib	5114	J1
21740	Reconstructive repair of pectus excavatum or carinatum; open	5114	J1
21750	Closure of median sternotomy separation with or without debridement (separate procedure)	5114	J1
21825	Open treatment of sternum fracture with or without skeletal fixation	5114	J1
22010	Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic	5114	J1
22015	Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral	5114	J1
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	5114	J1
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	5114	J1
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	5114	J1
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve	N/A	N

	root(s), single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)		
22206	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); thoracic	5114	J1
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); lumbar	5114	J1
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); each additional vertebral segment (list separately in addition to code for primary procedure)	N/A	N
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	5114	J1
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	5114	J1
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	5114	J1
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)	N/A	N
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical	5114	J1
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic	5114	J1
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	5114	J1
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	N/A	N
22318	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting	5115	J1
22319	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	5115	J1
22325	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar	5115	J1
22326	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; cervical	5115	J1

22327	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; thoracic	5115	J1
22328	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (list separately in addition to code for primary procedure)	N/A	N
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	5116	J1
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	5116	J1
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)	N/A	N
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-c1-c2 (atlas-axis), with or without excision of odontoid process	5116	J1
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	5116	J1
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	5116	J1
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	5116	J1
22590	Arthrodesis, posterior technique, craniocervical (occiput-c2)	5116	J1
22595	Arthrodesis, posterior technique, atlas-axis (c1-c2)	5116	J1
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment	5116	J1
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)	5116	J1
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	5116	J1
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)	N/A	N

22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments	5116	J1
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments	5116	J1
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments	5116	J1
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments	5116	J1
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments	5116	J1
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	5116	J1
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	5116	J1
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	5116	J1
22830	Exploration of spinal fusion	5115	J1
22841	Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)	N/A	N
22843	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)	N/A	N
22844	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)	N/A	N
22846	Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)	N/A	N
22847	Anterior instrumentation; 8 or more vertebral segments (list separately in addition to code for primary procedure)	N/A	N
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (list separately in addition to code for primary procedure)	N/A	N
22849	Reinsertion of spinal fixation device	5116	J1
22850	Removal of posterior nonsegmental instrumentation (for example, harrington rod)	5115	J1
22852	Removal of posterior segmental instrumentation	5115	J1
22855	Removal of anterior instrumentation	5115	J1
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar	5116	J1

22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	5116	J1
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	5116	J1
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	5115	J1
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	5115	J1
23200	Radical resection of tumor; clavicle	5114	J1
23210	Radical resection of tumor; scapula	5114	J1
23220	Radical resection of tumor, proximal humerus	5114	J1
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (for example, total shoulder)	5073	J1
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))	5115	J1
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	5115	J1
23900	Interthoracoscapular amputation (forequarter)	5115	J1
23920	Disarticulation of shoulder;	5115	J1
24900	Amputation, arm through humerus; with primary closure	5115	J1
24920	Amputation, arm through humerus; open, circular (guillotine)	5115	J1
24930	Amputation, arm through humerus; re-amputation	5114	J1
24931	Amputation, arm through humerus; with implant	5115	J1
24940	Cineplasty, upper extremity, complete procedure	5115	J1
25900	Amputation, forearm, through radius and ulna;	5115	J1
25905	Amputation, forearm, through radius and ulna; open, circular (guillotine)	5115	J1
25915	Krukenberg procedure	5114	J1
25920	Disarticulation through wrist;	5114	J1
25924	Disarticulation through wrist; re-amputation	5114	J1
25927	Transmetacarpal amputation;	5113	J1
26551	Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	5114	J1
26553	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	5114	J1
26554	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	5114	J1
26556	Transfer, free toe joint, with microvascular anastomosis	5114	J1
26992	Incision, bone cortex, pelvis and/or hip joint (for example, osteomyelitis or bone abscess)	5114	J1
27005	Tenotomy, hip flexor(s), open (separate procedure)	5114	J1

27025	Fasciotomy, hip or thigh, any type	5114	J1
27030	Arthrotomy, hip, with drainage (for example, infection)	5114	J1
27036	Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (ie, gluteus medius, gluteus minimus, tensor fascia latae, rectus femoris, sartorius, iliopsoas)	5114	J1
27054	Arthrotomy with synovectomy, hip joint	5113	J1
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); superficial	5114	J1
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); deep (subfascial or intramuscular)	5114	J1
27075	Radical resection of tumor; wing of ilium, 1 pubic or ischial ramus or symphysis pubis	5114	J1
27076	Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum	5114	J1
27077	Radical resection of tumor; innominate bone, total	5115	J1
27078	Radical resection of tumor; ischial tuberosity and greater trochanter of femur	5115	J1
27090	Removal of hip prosthesis; (separate procedure)	5073	J1
27091	Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer	5073	J1
27120	Acetabuloplasty; (for example, whitman, colonna, haygroves, or cup type)	5115	J1
27122	Acetabuloplasty; resection, femoral head (for example, girdlestone procedure)	5115	J1
27125	Hemiarthroplasty, hip, partial (for example, femoral stem prosthesis, bipolar arthroplasty)	5115	J1
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	5115	J1
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	5115	J1
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	5115	J1
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	5115	J1
27140	Osteotomy and transfer of greater trochanter of femur (separate procedure)	5115	J1
27146	Osteotomy, iliac, acetabular or innominate bone;	5114	J1
27147	Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	5114	J1
27151	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	5114	J1

27156	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip	5114	J1
27158	Osteotomy, pelvis, bilateral (for example, congenital malformation)	5114	J1
27161	Osteotomy, femoral neck (separate procedure)	5114	J1
27165	Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast	5114	J1
27170	Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	5114	J1
27175	Treatment of slipped femoral epiphysis; by traction, without reduction	5114	J1
27176	Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	5115	J1
27177	Open treatment of slipped femoral epiphysis; single or multiple pinning or bone graft (includes obtaining graft)	5114	J1
27178	Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	5114	J1
27181	Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	5114	J1
27185	Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	5114	J1
27187	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur	5114	J1
27222	Closed treatment of acetabulum (hip socket) fracture(s); with manipulation, with or without skeletal traction	5111	J1
27226	Open treatment of posterior or anterior acetabular wall fracture, with internal fixation	5114	J1
27227	Open treatment of acetabular fracture(s) involving anterior or posterior (one) column, or a fracture running transversely across the acetabulum, with internal fixation	5114	J1
27228	Open treatment of acetabular fracture(s) involving anterior and posterior (two) columns, includes t-fracture and both column fracture with complete articular detachment, or single column or transverse fracture with associated acetabular wall fracture, with internal fixation	5114	J1
27232	Closed treatment of femoral fracture, proximal end, neck; with manipulation, with or without skeletal traction	5112	J1
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	5114	J1
27240	Closed treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with manipulation, with or without skin or skeletal traction	5112	J1

27244	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with plate/screw type implant, with or without cerclage	5114	J1
27245	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	5114	J1
27248	Open treatment of greater trochanteric fracture, includes internal fixation, when performed	5114	J1
27253	Open treatment of hip dislocation, traumatic, without internal fixation	5113	J1
27254	Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation	5113	J1
27258	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	5113	J1
27259	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	5113	J1
27268	Closed treatment of femoral fracture, proximal end, head; with manipulation	5113	J1
27269	Open treatment of femoral fracture, proximal end, head, includes internal fixation, when performed	5112	J1
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed	5116	J1
27282	Arthrodesis, symphysis pubis (including obtaining graft)	5115	J1
27284	Arthrodesis, hip joint (including obtaining graft);	5116	J1
27286	Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	5116	J1
27290	Interpelviabdominal amputation (hindquarter amputation)	5116	J1
27295	Detachment of hip joint	5116	J1
27303	Incision, deep, with opening of bone cortex, femur or knee (for example, osteomyelitis or bone abscess)	5114	J1
27365	Radical resection of tumor, femur or knee	5114	J1
27445	Arthroplasty, knee, hinge prosthesis (for example, walldius type)	5115	J1
27448	Osteotomy, femur, shaft or supracondylar; without fixation	5114	J1
27450	Osteotomy, femur, shaft or supracondylar; with fixation	5114	J1
27454	Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (for example, sofield type procedure)	5114	J1
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus	5114	J1

	[bowleg] or genu valgus [knock-knee]); before epiphyseal closure		
27457	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure	5114	J1
27465	Osteoplasty, femur; shortening (excluding 64876)	5114	J1
27466	Osteoplasty, femur; lengthening	5114	J1
27468	Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	5114	J1
27470	Repair, nonunion or malunion, femur, distal to head and neck; without graft (for example, compression technique)	5114	J1
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	5114	J1
27486	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	5115	J1
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	5115	J1
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	5114	J1
27495	Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur	5114	J1
27506	Open treatment of femoral shaft fracture, with or without external fixation, with insertion of intramedullary implant, with or without cerclage and/or locking screws	5114	J1
27507	Open treatment of femoral shaft fracture with plate/screws, with or without cerclage	5114	J1
27511	Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	5114	J1
27513	Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	5114	J1
27514	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	5114	J1
27519	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	5114	J1
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	5114	J1
27536	Open treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal fixation	5114	J1

27540	Open treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, includes internal fixation, when performed	5114	J1
27556	Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	5114	J1
27557	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	5114	J1
27558	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	5114	J1
27580	Arthrodesis, knee, any technique	5115	J1
27590	Amputation, thigh, through femur, any level;	5116	J1
27591	Amputation, thigh, through femur, any level; immediate fitting technique including first cast	5116	J1
27592	Amputation, thigh, through femur, any level; open, circular (guillotine)	5116	J1
27596	Amputation, thigh, through femur, any level; re-amputation	5114	J1
27598	Disarticulation at knee	5115	J1
27645	Radical resection of tumor; tibia	5114	J1
27646	Radical resection of tumor; fibula	5114	J1
27702	Arthroplasty, ankle; with implant (total ankle)	5115	J1
27703	Arthroplasty, ankle; revision, total ankle	5115	J1
27712	Osteotomy; multiple, with realignment on intramedullary rod (for example, sofield type procedure)	5115	J1
27715	Osteoplasty, tibia and fibula, lengthening or shortening	5115	J1
27724	Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	5114	J1
27725	Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	5114	J1
27727	Repair of congenital pseudarthrosis, tibia	5114	J1
27880	Amputation, leg, through tibia and fibula;	5116	J1
27881	Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast	5114	J1
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)	5114	J1
27886	Amputation, leg, through tibia and fibula; re-amputation	5114	J1
27888	Amputation, ankle, through malleoli of tibia and fibula (for example, syme, pirogoff type procedures), with plastic closure and resection of nerves	5115	J1
28800	Amputation, foot; midtarsal (for example, chopart type procedure)	5113	J1

G0412	Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s), unilateral or bilateral for pelvic bone fracture patterns which do not disrupt the pelvic ring includes internal fixation, when performed	5114	J1
G0414	Open treatment of anterior pelvic bone fracture and/or dislocation for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation when performed (includes pubic symphysis and/or superior/inferior rami)	5115	J1
G0415	Open treatment of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation, when performed (includes ilium, sacroiliac joint and/or sacrum)	5115	J1
00192	Anesthesia for procedures on facial bones or skull; radical surgery (including prognathism)	N/A	N
00474	Anesthesia for partial rib resection; radical procedures (eg, pectus excavatum)	N/A	N
00604	Anesthesia for procedures on cervical spine and cord; procedures with patient in the sitting position	N/A	N
01756	Anesthesia for open or surgical arthroscopic procedures of the elbow; radical procedures	N/A	N
01638	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement	N/A	N
01636	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; interthoracoscapular (forequarter) amputation	N/A	N
01634	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; shoulder disarticulation	N/A	N
01150	Anesthesia for radical procedures for tumor of pelvis, except hindquarter amputation	N/A	N
01140	Anesthesia for interpelviabdominal (hindquarter) amputation	N/A	N
01212	Anesthesia for open procedures involving hip joint; hip disarticulation	N/A	N
01234	Anesthesia for open procedures involving upper two-thirds of femur; radical resection	N/A	N
01232	Anesthesia for open procedures involving upper two-thirds of femur; amputation	N/A	N
01404	Anesthesia for open or surgical arthroscopic procedures on knee joint; disarticulation at knee	N/A	N
01486	Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement	N/A	N

01274	Anesthesia for procedures involving arteries of upper leg, including bypass graft; femoral artery embolectomy	N/A	N
00904	Anesthesia for; radical perineal procedure	N/A	N
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	5184	J1
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	5184	J1
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)	5193	J1
37617	Ligation, major artery (eg, post-traumatic, rupture); abdomen	5183	J1
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	5362	J1
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	5331	J1
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)	5302	J1
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	5055	T
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	5341	J1
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	5341	J1
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	5303	J1
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	5341	J1
49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	5341	J1
51840	Anterior vesicourethropexy, or urethropexy (eg, marshall-marchetti-krantz, burch); simple	5415	J1
56630	Vulvectomy, radical, partial;	5415	J1
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	5194	J1

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4. Topics and Questions Posed for Public Comments

In addition to our proposal to halt the elimination of the IPO list and return services summarily removed from the IPO list last year that our clinicians have determined do not meet the criteria for removal from the IPO list, as provided in Table 35, we are also interested in feedback from stakeholders on whether CMS should maintain the longer-term objective of eliminating the IPO list or if CMS should maintain the IPO list but continue to systematically scale the list back to so that inpatient only designations are consistent with current standards of practice. Specifically, CMS is requesting comments on the following:

- Should CMS maintain the longer-term objective of eliminating the IPO list? If so, what is a reasonable timeline for eliminating the list? What method do stakeholders suggest CMS use to approach removing codes from the list?
- Should CMS maintain the IPO list but continue to streamline the list of services included on the list and, if so, suggestions for ways to systematically scale the list back to allow for the removal of codes, or groups of codes, that can safely and effectively be performed on a typical Medicare beneficiary in the hospital outpatient setting so that inpatient only designations are consistent with current standards of practice?
- What effect do commenters believe the elimination or scaling back of the IPO list would have on safety and quality of care for Medicare beneficiaries?
- What effect do commenters believe elimination or the scaling back of the IPO list would have on provider behavior, incentives, or innovation?
- What information or support would be helpful for providers and physicians in their considerations of site-of-service selections?
- Should CMS's clinical evaluation of the safety of a service in the outpatient setting consider the safety and quality of care for the typical Medicare beneficiary or a smaller subset of Medicare beneficiaries for whom the outpatient provision of a service may have fewer risk factors?
- Are there services that were removed from the IPO list in CY 2021 that stakeholders believe meet the longstanding criteria for removal from the IPO list and should continue to be payable in the outpatient setting in CY 2022? If so, what evidence supports the conclusion that the service meets the longstanding criteria for removal from the IPO list and is safe to perform on the Medicare population in the outpatient setting?

X. Proposed Nonrecurring Policy Changes

A. Proposed Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2022 and Subsequent Years

1. Background on the 2-Midnight Rule

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we clarified our policy regarding when an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment. Under this policy, we established a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not designated as an inpatient-only (IPO) procedure as described in 42 CFR 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed. With respect to services designated under the OPPS as IPO list procedures, we explained that because of the intrinsic risks, recovery impacts, or complexities associated with such services, these procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. We also indicated that there might be further ''rare and unusual'' exceptions to the application of the benchmark, which would be detailed in subregulatory guidance.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we also finalized the 2-Midnight presumption, which is related to the 2-Midnight benchmark but is a separate medical review policy. The 2-Midnight benchmark represents guidance to reviewers to identify when an inpatient admission is generally reasonable and necessary for purposes of Medicare Part A payment, while the 2-Midnight presumption relates to instructions to medical reviewers regarding the selection of claims for medical review. Specifically, under the 2-Midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and are not the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-Midnight presumption.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70549), we revisited the previous rare and unusual exceptions policy and finalized a proposal to allow for case-by-case exceptions to the 2-Midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's determination that the patient nonetheless requires inpatient hospital care.

In the CY 2016 OPPS/ASC final rule with comment period, we reiterated our position that the 2-Midnight benchmark provides clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of physician judgment. We stated that the following criteria will be relevant to determining whether an inpatient admission with an expected length of stay of less than 2 midnights is nonetheless appropriate for Medicare Part A payment:

- Complex medical factors such as history and comorbidities;
- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

The exceptions for procedures on the IPO list and for ''rare and unusual'' circumstances designated by CMS as national exceptions were unchanged by the CY 2016 OPPS/ASC final rule with comment period.

As we stated in the CY 2016 OPPS/ASC final rule with comment period, the decision to formally admit a patient to the hospital is subject to medical review. For instance, for cases where the medical record does not support a reasonable expectation of the need for hospital care crossing at least 2 midnights, and for inpatient admissions not related to a surgical procedure specified by Medicare as an IPO procedure under 42 CFR 419.22(n) or for which there is not a national exception, payment of the claim under Medicare Part A is subject to the clinical judgment

of the medical reviewer. The medical reviewer's clinical judgment involves the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation) to make a medical review determination on whether the clinical requirements in the relevant policy have been met. In addition, Medicare review contractors must abide by CMS' policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision. While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors. This type of information also may be appropriately considered by the physician as part of the complex medical judgment that guides their decision to keep a beneficiary in the hospital and formulation of the expected length of stay.

2. Current Policy for Medical Review of Inpatient Hospital Admissions for Procedures Removed From the Inpatient Only List

In the CY 2020 OPPS/ASC final rule with comment period we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities to assess compliance with the 2-Midnight rule within the 2 calendar years following their removal from the IPO list. We stated that these procedures will not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-Midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for ''patient status.'' We explained that during this 2-year period, BFCC–QIOs will have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A.

In CY 2021 we proposed to continue the 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. However, we finalized our proposal with modifications in the CY 2021 OPPS/ASC final rule with comment period. Instead of the 2-year exemption, procedures removed from the IPO list after January 1, 2021 were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service). We stated that this exemption would last until we have Medicare claims data indicating that the procedure is more commonly performed in the outpatient setting than the inpatient setting. Thus, for the exemption to end for a specific procedure, in a single calendar year we would need to have Medicare claims data indicating that the procedure was performed more than 50 percent of the time in the outpatient setting. We stated that we would revisit in rulemaking whether an exemption for a procedure should be ended or whether we may consider additional metrics in the future that could assist us in determining when the exemption period should end for a procedure. Even during this exemption period, the BFCC–QIOs retain the authority to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A. Additionally, we stated that we may still conduct medical review in cases in which we believe there is potential fraud or abuse occurring. We explained that the elimination of the IPO list was a large scale change that created brand new considerations in determining site-of-service for providers and beneficiaries. At the time we believed a change of this significance required us to reevaluate our stance on the exemption period for procedures removed from the IPO list.

Finally, in the CY 2021 OPPS/ASC final rule with comment period we amended 42 CFR 412.3 to clarify when a procedure removed from the IPO is exempt from certain medical review activities. We stated that for those services and procedures removed between January 1 and December 31, 2020, this exemption will last for 2 years from the date of such removal. For those services and procedures removed on or after January 1, 2021, this exemption will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting.

3. Medical Review of Inpatient Hospital Admissions for Procedures Removed From the Inpatient Only List for CY 2022 and Subsequent Years

As stated earlier in this section, services on the IPO list are not subject to the 2-Midnight rule for purposes of determining whether payment is appropriate under Medicare Part A. However, the 2-Midnight rule is applicable once services have been removed from the IPO list. Outside of the exemption periods discussed above, services that have been removed from the IPO list are subject to initial medical reviews of claims for short-stay inpatient admissions conducted by BFCC–QIOs.

BFCC–QIOs may also refer providers to the RACs for further medical review due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to:

- Having high denial rates;
- Consistently failing to adhere to the 2-Midnight rule; or
- Failing to improve their performance after QIO educational intervention.

However, as finalized in the CY 2021 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list January 1, 2021 or later were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service). We stated that this exemption would last until we have Medicare claims data indicating that the procedure is more commonly performed in the outpatient setting than the inpatient setting.

As stated in section IX, CMS is proposing to halt the elimination of the IPO list. In accordance with this proposal, we are proposing to amend 42 CFR 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a three-year transition. We are also proposing to return 298 procedures removed from the IPO list in CY 2021 to the IPO list for CY 2022.

Regardless of the status of the IPO list, we believe that the 2-Midnight benchmark remains an important metric to help guide when Part A payment for inpatient hospital admissions is appropriate. As technology advances and more services may be safely performed in the hospital outpatient setting and paid under the OPPS, it is

increasingly important for physicians to exercise their clinical judgment in determining the generally appropriate clinical setting for their patient to receive a procedure, whether that be as an inpatient or on an outpatient basis. Importantly, removal of a service from the IPO list has never meant that a beneficiary cannot receive the service as a hospital inpatient—as always, the physician should use his or her complex medical judgment to determine the appropriate setting on a case by case basis.

As stated previously, our current policy regarding IPO list procedures is that they are appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. Halting the elimination of the IPO list would mean that this will remain true for all services that are still on the list. As in previous years, any services that are removed from the list in the future will be subject to the 2-Midnight benchmark and 2-Midnight presumption. This means that for services removed from the IPO list, under the 2-Midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after admission will be presumed to be appropriate for Medicare Part A payment and would not be the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-Midnight presumption. Additionally, under the 2-Midnight benchmark, services formerly on the IPO list will be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.

As finalized in the CY 2021 OPPS/ASC final rule with comment period, procedures removed from the IPO list after January 1, 2021 were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service). These procedures are not considered by the BFCC–QIOs in determining whether a provider exhibits persistent noncompliance with the 2-Midnight rule for purposes of referral to the RAC nor will claims for these procedures be reviewed by RACs for ''patient status.'' During the exemption period, BFCC–QIOs have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant are not denied with respect to the site-of-service under Medicare Part A. Again, information gathered by the BFCC–QIO when reviewing procedures as they are newly removed from the IPO list can be used for educational purposes and does not result in a claim denial during the exemption period.

Because we are proposing to halt the elimination of the IPO list and add 298 services that were removed back to the IPO list, we believe this proposed change requires us to reexamine the applicable exemption period. We noted in the CY 2021 OPPS/ASC final rule with comment period that we may shorten the exemption period for a procedure if necessary. We heard from many commenters last year that the 2-year exemption was appropriate when CMS was removing a smaller volume of procedures from the IPO list. However, commenters believed that the unprecedented volume of procedures becoming subject to the 2-Midnight rule with the phased elimination of the IPO list would necessitate a longer exemption period. While these commenters expressed their support for continuing the 2-year exemption, they further stated that a longer exemption period may be more appropriate. Some commenters suggested that anywhere between 3 to 6 years or indefinitely would be appropriate. Commenters expressed their belief that increasing the length of the exemption would be necessary to allow hospitals and practitioners sufficient time to adjust their billing and clinical systems, as well as processes used to determine the appropriate setting of care. For a full description of the comments received please refer to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86115).

We believe that the indefinite exemption was appropriate when the agency was removing an unprecedented volume of procedures from the IPO list in a short period of time. That would have resulted in a large number of procedures becoming subject to the 2-Midnight rule in a three-year span. However, should we finalize our proposal to halt the elimination of the IPO list, there will no longer be an unprecedented volume of procedures removed from the IPO list at once, and thus the indefinite exemption may no longer be appropriate. As we explained in the CY 2021 OPPS/ASC final rule with comment period, the indefinite exemption was necessary given the magnitude of the change for providers. Now, however, we are proposing to move toward a much smaller volume of procedures becoming subject to the 2-Midnight rule at one time. We believe that, in the event that we finalize the proposed halt in the elimination of the IPO list, an indefinite exemption from medical review activities related to the 2-Midnight rule will no longer be warranted.

We continue to believe that, in order to facilitate compliance with our payment policy for inpatient admissions, some exemption from certain medical review activities for services removed from the IPO list under the OPPS is appropriate. Accordingly, we propose to rescind the indefinite exemption and instead apply a 2-year exemption from two midnight medical review activities for services removed from the IPO list on or after January 1, 2021. As finalized in the CY 2020 OPPS/ASC final rule with comment period, and unchanged by the CY 2021 rulemaking, services removed from the IPO list between January 1 and December 30, 2020, are currently subject to a 2-year exemption. Accordingly, under this proposal, the same 2-year exemption would apply to all service removed from the IPO list on or after January 1, 2020. As we explained in the CY 2020 OPPS/ASC final rule with comment period, we believe that a 2-year exemption from certain medical review activities for procedures removed from the IPO list would allow sufficient time for providers to become more familiar with how to comply with the 2-Midnight rule and for hospitals and clinicians to become used to the availability of payment under both the hospital inpatient and outpatient setting for procedures removed from the IPO list. Should we finalize our proposal to halt the elimination of the IPO list, we believe that this rationale applies equally to the smaller number of services that may be removed from the list at any one time in the future, and thus that the same 2-year exemption period is appropriate.

As with the previous 2-year exemption period for services removed from the IPO list between January 1 and December 30, 2020, applying a 2-year exemption period to services removed from the IPO list on or after January 1, 2021, would allow providers time to gather information on procedures newly removed from the IPO list to help inform education and guidance for the broader provider community, develop patient selection criteria to identify which patients are, and are not, appropriate candidates for outpatient procedures, and to develop related policy protocols. We believe that this exemption period would aid in

compliance with our payment policy for inpatient admissions.

It is important to note that whether there is a limited timeframe or an indefinite exemption from the specified medical review activities, providers are still expected to comply with the 2-Midnight rule. It is also important to note that the 2-Midnight rule does not prohibit procedures from being performed or billed on an inpatient basis. Whether a procedure has an exemption or not does not change what site of service is medically necessary or appropriate for an individual beneficiary. Providers are still expected to use their complex medical judgment to determine the appropriate site of service for each patient and to bill in compliance with the 2-Midnight rule. The exemption is not from the 2-Midnight rule but from certain medical review procedures and site-of-service claim denials.

Absent the removal of an unprecedented number of services at once from the IPO list, we continue to believe that a 2-year exemption from BFCC–QIO referral to RACs and RAC ''patient status'' review of the setting for procedures removed from the IPO list under the OPPS and performed in the inpatient setting would be an adequate amount of time to allow providers to gain experience with application of the 2-Midnight rule to these procedures and the documentation necessary for Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting. Furthermore, it is our belief that the 2-year exemption from referrals to RACs, RAC patient status review, and claims denials would be sufficient to allow providers time to update their billing systems and gain experience with respect to newly removed procedures eligible to be paid under either the IPPS or the OPPS, while avoiding potential adverse site-of-service determinations. We solicit public comments regarding the appropriate period of time for this exemption. Commenters may indicate whether and why they believe the 2-year period is appropriate, or whether they believe a longer or shorter exemption period would be more appropriate.

In summary, for CY 2021 and subsequent years, we propose to return to the 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS on January 1, 2021 or later. Under this proposal, services removed beginning on January 1, 2021 would receive the same 2-year exemption from 2-Midnight medical review activities as currently applies to services removed between January 1 and December 30, 2020, and not the indefinite exemption finalized in the CY 2021 OPPS/ASC final rule with comment period. We encourage BFCC–QIOs to review these cases for medical necessity in order to educate themselves and the provider community on appropriate documentation for Part A payment when the admitting physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis. We note that we will monitor changes in site-of-service to determine whether changes may be necessary to certain CMS Innovation Center models. While we are proposing to halt the elimination of the IPO list, we are seeking comment on whether a 2-year time period is appropriate, or if a longer or shorter period may be more warranted. If we do not finalize our proposal to halt the elimination of the IPO list we may continue with the indefinite exemptions. Finally, we are proposing to amend § 412.3 of the Code of Federal Regulations to clarify when a procedure removed from the IPO list is exempt from certain medical review activities. For all services and procedures removed after January 1, 2020, this exemption will last for 2 years from the date of such removal. This would include those services and procedures removed on or after January 1, 2021, for which this exemption would also be for 2 years from the date of such removal.

B. Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. The reduced coinsurance will be phased in beginning January 1, 2022. Currently, the addition of any procedure beyond a planned colorectal cancer screening test (for which there is no coinsurance), results in the beneficiary having to pay coinsurance.

Section 1861(pp) of the Act defines ''colorectal cancer screening tests'' and, under sections 1861(pp)(1)(B) and (C) of the Act, identifies ''screening flexible sigmoidoscopy'' and ''screening colonoscopy'' as two of the recognized procedures. During the course of either one of these two procedures, removal of tissue or other matter may become necessary for diagnostic purposes. Among other things, section 1861(pp)(1)(D) of the Act authorizes the Secretary to include in the definition, other tests or procedures and modifications to the tests and procedures described under this subsection, with such frequency and payment limits as the Secretary determines appropriate, in consultation with appropriate organizations. Section 1861(s)(2)(R) of the Act includes colorectal cancer screening tests in the definition of the medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(ddd)(3) of the Act includes colorectal cancer screening tests within the definition of ''preventive services.'' In addition, section 1833(a)(1)(Y) of the Act provides for payment for a preventive service under the PFS at 100 percent of the lesser of the actual charge or the fee schedule amount for these colorectal cancer screening tests, and under the OPPS at 100 percent of the OPPS payment amount, when the preventive service is recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. As such, there is no beneficiary coinsurance for recommended colorectal cancer screening tests as defined in section 1861(pp)(1) of the Act.

Under these statutory provisions, we have issued regulations governing payment for colorectal cancer screening tests at § 410.152(l)(5). We pay 100 percent of the Medicare payment amount established under the applicable payment methodology for the setting for providers and suppliers, and beneficiaries are not required to pay Part B coinsurance for colorectal cancer screening tests (except for barium enemas, which are not recommended by the USPSTF with a grade of A or B).

In addition to colorectal cancer screening tests, which typically are furnished to patients in the absence of signs or symptoms of illness or injury, Medicare also covers various diagnostic tests (see § 410.32). In general, diagnostic tests must be ordered by the physician or practitioner who is treating the beneficiary and who uses the results of the diagnostic test in the management of the patient's specific medical

condition. Under Part B, Medicare may cover flexible sigmoidoscopies and colonoscopies as diagnostic tests when those tests are reasonable and necessary as specified in section 1862(a)(1)(A) of the Act. When these services are furnished as diagnostic tests rather than as screening tests, patients are responsible for the 20 percent of the Part B coinsurance associated with these services.

We define colorectal cancer screening tests in our regulation at § 410.37(a)(1) to include ''flexible screening sigmoidoscopies'' and ''screening colonoscopies, including anesthesia furnished in conjunction with the service.'' Under our current regulations, we exclude from the definition of colorectal screening services, colonoscopies and sigmoidoscopies that begin as screening services, but where a polyp or other growth is found and removed as part of the procedure. The exclusion of these services from the definition of colorectal cancer screening services is based upon longstanding provisions of the statute under section 1834(d)(2)(D) dealing with the detection of lesions or growths during procedures (See CY 1998 PFS final rule at 62 FR 59048, 59082).

Prior to the enactment of section 122 of the CAA, section 1834(d)(2)(D) of the Act provided that if, during the course of a screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy, but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. Similarly, prior to the recent legislative change, section 1834(d)(3)(D) of the Act provided that if, during the course of a screening colonoscopy, a lesion or growth is detected that results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal. In these situations, Medicare pays for the flexible sigmoidoscopy and colonoscopy tests as diagnostic tests rather than as screening tests and the 100 percent payment rate for recommended preventive services under section 1833(a)(1)(Y) of the Act, as codified in our regulation at § 410.152(l)(5), has not applied. As such, beneficiaries currently are responsible for the usual 20 percent coinsurance that applies to the services.

Under section 1833(b) of the Act, before making payment under Medicare Part B for expenses incurred by a beneficiary for covered Part B services, beneficiaries must first meet the applicable deductible for the year. Section 4104 of the Affordable Care Act (that is, the Patient Protection and Affordable Care Act (Pub. L. 111–148, March 23, 2010), and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, March 30, 2010), collectively referred to as the ''Affordable Care Act'') amended section 1833(b)(1) of the Act to make the deductible inapplicable to expenses incurred for certain preventive services that are recommended with a grade of A or B by the USPSTF, including colorectal cancer screening tests as defined in section 1861(pp) of the Act. Section 4104 of the Affordable Care Act also added a sentence at the end of section 1833(b)(1) of the Act specifying that the exception to the deductible shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. Although amendments made by the Affordable Care Act addressed the applicability of the deductible in the case of a colorectal cancer screening test that involves biopsy or tissue removal, they did not alter the coinsurance provision in section 1833(a) of the Act for such procedures. Although public commenters encouraged the agency to eliminate the coinsurance in these circumstances, the agency found that statute did not provide for elimination of the coinsurance (75 FR 73170 at 73431).

Beneficiaries have continued to contact us noting their concern that a coinsurance percentage applies (20 or 25 percent depending upon the setting) under circumstances where they expected to receive only a colorectal screening test to which coinsurance does not apply. Instead, these beneficiaries received what Medicare considers to be a diagnostic procedure because, for example, polyps were discovered and removed during the procedure. Similarly, physicians have expressed concern about the reactions of beneficiaries when they are informed that they will be responsible for coinsurance if polyps are discovered and removed during a procedure that they had expected to be a screening procedure to which coinsurance does not apply.

Section 122 of the CAA addresses this coinsurance issue by successively reducing, over a period of years, the percentage amount of coinsurance for which the beneficiary is responsible. Ultimately, for services furnished on or after January 1, 2030, the coinsurance will be zero.

To implement the amendments made by section 122 of the CAA, we are proposing in the CY 2022 PFS proposed rule to modify our regulations to reflect the changes to statute. As amended, the statute effectively provides that, for services furnished on or after January 1, 2022, a flexible sigmoidoscopy or a colonoscopy can be considered a screening flexible sigmoidoscopy or a screening colonoscopy test even if an additional procedure is furnished to remove tissue or other matter during the screening test. Specifically, section 122(a)(3) of the CAA added a sentence to the end of section 1833(a) of the Act to include as colorectal screening tests described in section 1833(a)(1)(Y) of the Act, a colorectal cancer screening test, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. We note that only flexible screening sigmoidoscopies and screening colonoscopies are recognized currently as colorectal cancer screening tests that might involve removal of tissue or other matter. This new sentence added under section 1833(a) uses the same language that was used to amend the statute at section 1833(b)(1) of the Act to broaden the scope of colorectal cancer screening tests to which a deductible does not apply. Section 122(b)(1) of the CAA then limits application of the 100 percent Medicare payment rate (that is, no beneficiary coinsurance) under section 1833(a)(1)(Y) of the Act for the additional colorectal cancer screening tests (those that are not screening tests ''but for'' the new sentence at the end of section 1833(a) of the Act) by making payment for them subject to a new section 1833(dd) of the Act. Section 1833(dd) of the Act provides for a series of increases in the Medicare payment rate percentage for those services over successive periods of years through CY 2029. Thereafter, section 1833(dd) of the Act has no effect, so payment for all colorectal cancer screening tests would be made at 100 percent under section 1833(a)(1)(Y) of the Act.

To codify the amendments made by section 122 of the CAA in our regulations, we are proposing in the CY 2022 PFS proposed rule to make two modifications to current regulations.

At § 410.37, we propose in the CY 2022 PFS proposed rule to modify our

regulation where we define conditions for and limitations on coverage for colorectal cancer screening tests by adding a new paragraph (j). That paragraph would provide that, effective January 1, 2022, when a planned colorectal cancer screening test, that is, screening flexible sigmoidoscopy or colonoscopy screening test, requires a related procedure, including removal of tissue or other matter, furnished in connection with, as a result of, and in the same clinical encounter as the screening test, it is considered to be a colorectal cancer screening test.

At § 410.152(l)(5), we propose in the CY 2022 PFS proposed rule to modify our regulation. Here we describe payment for colorectal cancer screening tests. Effective January 1, 2022, we propose to provide for an increase in the Medicare payment percentage that is phased in over time. As the Medicare payment percentage increases, the beneficiary coinsurance percentage decreases. We propose to revise section 410.152(l)(5) to provide that Medicare payment in a specified year is equal to a specified percent of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to the test. The phased in Medicare payment percentages for colorectal cancer screening services described in the amendments we propose in the CY 2022 PFS proposed rule to our regulation at section 410.37(j) (and the corresponding reduction in coinsurance) are as follows:

- 80 percent payment for services furnished in CY 2022 (with coinsurance equal to 20 percent);
- 85 percent payment for services furnished in CY 2023 (with coinsurance equal to 15 percent);
- 90 percent payment for services furnished in 2027 through 2029 (with coinsurance equal to 10 percent); and
- 100 percent payment for services furnished from CY 2030 onward (with coinsurance equal to zero percent).

Thus, between CYs 2022 and 2030, the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter will be reduced from 20 or 25 percent to 0 percent. We refer readers to the CY 2022 Medicare Physician Fee Schedule (PFS) proposed rule for the full discussion of these proposed changes. Comments on this proposed policy, including the proposed changes to the regulations at §§ 410.37 and 410.152(l)(5), should be submitted in response to the CY 2022 PFS proposed rule.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72019 through 72020), we adopted a policy that all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of implementing section 4104(c)(2) of the Affordable Care Act. We created the HCPCS modifier PT for providers to append to the diagnostic procedure code that is reported instead of the screening colonoscopy, screening flexible sigmoidoscopy HCPCS code, or as a result of the barium enema when the screening test becomes a diagnostic service. Where the modifier appears on a claim, the claims processing system does not apply the Part B deductible for all surgical services on the same date as the diagnostic test. We stated that we believed this interpretation was appropriate because we believe that it would be very rare for an unrelated surgery to occur on the same date as one of these scheduled screening tests (75 FR 72019). We also stated that we would reassess the appropriateness of the proposed definition of services that are furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test that becomes diagnostic in the event of a legislative change to this policy (for example, a statutory change that would remove the coinsurance for these related services in addition to the deductible).

As we did for purposes of implementing section 4104(c)(2) of the Affordable Care Act, to implement the amendments made by section 122 of the CAA we propose that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy would be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test for purposes of determining the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter. We believe this interpretation is appropriate because we continue to believe that it is very rare for an unrelated surgery to occur on the same date as a scheduled colorectal cancer screening. Providers must continue to report HCPCS modifier ''PT'' to indicate that a planned colorectal cancer screening service converted to a diagnostic service. We note that if this proposal is finalized, we will examine the claims data, monitor for any increases in surgical services unrelated to the colorectal cancer screening test performed on the same date as the screening test, and consider revising our policy through rulemaking if there is a notable increase.

C. Low Volume Policy for Clinical, Brachytherapy, and New Technology APCs

Historically, we have used our equitable adjustment authority at section 1833(t)(2)(E) of the Act on a case-by-case basis to adjust how we determine the costs for certain low volume services. In the CY 2016 OPPS/ASC final rule with comment period, we acknowledged that for low volume procedures with significant device costs, the median cost would be a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for low volume procedures (80 FR 70388 through 70389). We explained that the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. Therefore, in the CY 2016 OPPS/ASC final rule with comment period, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to use the median cost, rather than the geometric mean, to calculate the payment rate for the procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) for CY 2016.

In the CY 2017 OPPS/ASC final rule with comment period, we adopted a payment policy for low-volume device-intensive procedures similar to the policy we applied to the procedure described by CPT code 0308T. Under this policy, we calculate the payment rate for any device-intensive procedure that is assigned to an APC with fewer than 100 single claims for all procedures in the APC using the median cost instead of the geometric mean cost (81 FR 79660 through 79661). We explained that we believed this policy would help mitigate to some extent the significant year-to-year payment rate fluctuations while preserving accurate claims data-based payment rates for these procedures.

In the CY 2019 OPPS/ASC final rule with comment period, we developed a policy for establishing payment rates for low-volume procedures assigned to New Technology APCs (83 FR 58892 through 58893). In that rule, we explained that procedures assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them (83 FR 58892). 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. We stated that some procedures that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. There is a higher probability that payment data for a procedure with fewer than 100 claims per year may not have a normal statistical distribution, which we were concerned could affect the quality of our standard cost methodology for assigning services to clinical APCs. We also noted that services with fewer than 100 claims per year are not generally considered to be significant contributors to the APC ratesetting calculations, and therefore, are not included in the assessment of the 2 times rule. For these low-volume procedures, we were concerned that the methodology we use to estimate the cost of a procedure under the OPPS—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 these procedures.

We noted that low utilization of services can lead to wide variation in payment rates from year to year. This volatility in payment rates from year to year can result in even lower utilization and potential barriers to access for these new technologies, which in turn limits our ability to assign the service to an appropriate clinical APC. To mitigate these issues, we believed that it was 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 finalized a policy to calculate payment rates for low-volume procedures with fewer than 100 claims per year that are assigned to a New Technology APC by using up to 4 years of claims data to calculate the geometric mean, the median, and the arithmetic mean, to include the result of each statistical methodology in annual rulemaking, and to solicit comment on which methodology should be used to establish the payment rate. We explained that once we identify a payment rate for a low-volume service, we would assign the service to the New Technology APC with the cost band that includes its payment rate (83 FR 58893).

While we believe that the policies we have adopted to calculate payment rates for low-volume procedures have mitigated concerns regarding payment rates for new technologies and device-intensive procedures, we also believe that additional items and services may benefit from a policy that applies to clinical APCs with significantly low claims volume available for ratesetting purposes. In particular, we believe that where there are fewer than 100 single claims from the most recent year available for ratesetting for an APC, there is often significant volatility in the payment rate for those APCs that could be addressed with a low-volume adjustment policy similar to our low-volume policies for device-intensive procedures and New Technology APCs. For example, for CY 2022 ratesetting purposes, there are only 43 single claims from CY 2019 available for determining the geometric mean cost for APC 5244 (Level 4 Blood Product Exchange and Related Services) and the payment rate for this APC has fluctuated significantly from year to year. The geometric mean cost of APC 5244 was $30,424.15 in CY 2018 (based on CY 2016 claims), increased by 25.6 percent to $38,220.27 in CY 2019 (based on CY 2017 claims), and decreased by 18.9 percent to $31,015.17 in CY 2021 (based on CY 2019 claims).

Additionally, for CY 2022 ratesetting purposes, there are only 22 single claims from CY 2019 available for determining the geometric mean cost of APC 2632 (Iodine i-125 sodium iodide). The payment rates for this APC have also fluctuated significantly, with a geometric mean cost of $26.63 in CY 2018 (based on CY 2016 claims), which increased by 43.4 percent to $38.20 in CY 2019 (based on CY 2017 claims), and decreased by 31.8 percent to $26.04 in CY 2021 (based on CY 2019 claims).

We believe that APCs with low claims volume available for ratesetting could also benefit from a low-volume adjustment policy similar to the one we currently utilize to set payment rates for device-intensive procedures and procedures assigned to New Technology APCs. Specifically, we propose to designate clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year (the CY 2019 claims year for this CY 2022 proposed rule) as low volume APCs. While our proposed criterion for a clinical or brachytherapy APC to qualify as a low volume APC policy is that the APC have fewer than 100 single claims that can be used for ratesetting, we acknowledge that New Technology APCs are different from clinical APCs in that they contain procedures that may not be clinically similar to other procedures assigned to the same New Technology APC based on cost and are only assigned to a New Technology APC because there is not sufficient data to assign these procedures to a clinical APC. Therefore, we propose that for New Technology APCs with fewer than 100 single claims at the procedure level that can be used for ratesetting, we would apply our proposed methodology for determining a low volume APC's cost, choosing the ''greatest of'' the median, arithmetic mean, or geometric mean at the procedure level, to apply to the individual services assigned to New Technology APCs and provide the final New Technology APC assignment for each procedure.

We are proposing that the threshold for the low volume APC designation would be fewer than 100 single claims per year for the APC that can be used for ratesetting purposes, as this is how we have traditionally defined low volume under our existing policies. As previously mentioned, the threshold would be 100 single claims at the procedure level for New Tech APCs. We have defined low volume as fewer than 100 single claims under our existing policies as there is a higher probability that payment data for a procedure with fewer than 100 claims per year may not have a normal statistical distribution, which we were concerned could affect how we set payment rates for low volume APCs. For items and services assigned to APCs we propose to designate as low volume APCs, we are proposing to use up to 4 years of claims data to establish a payment rate for each item or service as we currently do for low volume services assigned to New Technology APCs. The availability of multiple years of claims data will allow for more claims to be used for ratesetting purposes and create a more statistically reliable payment rate for these APCs than setting rates for APCs with low claims volume based on one year of data alone. Further, using multiple years of claims data, we are proposing to use the greatest of the median, arithmetic mean, or geometric mean cost to approximate the cost of items and services assigned to a low volume APC. In previous years, we have received few to no public comments on which statistical methodology to use and have usually chosen the methodology that yields the highest rate to set the payment rate for procedures assigned to New Technology APCs. Going forward, we are proposing to formalize this approach for low volume New Technology, clinical, and brachytherapy APCs, as we believe using the greatest of these three methodologies provides a simple and consistent approach to determining the cost metric to be used for ratesetting for

these APCs and avoids uncertainty where multiple cost metrics could be used to set the APC's cost. Additionally, due to the payment volatility and low volume nature of these products, we believe that choosing the methodology that yields the highest rate will ensure that these products receive sufficient payment and that payment is not a barrier to access for these procedures.

Given the different nature of policies that affect the partial hospitalization program (PHP), we are not proposing to apply this low volume APC policy to APC 5853 Partial Hospitalization for CMHCs or APC 5863 Partial Hospitalization for Hospital-based PHPs. We are also not proposing to apply this low volume APC policy to APC 2698 (Brachytx, stranded, nos) or APC 2699 (Brachytx, non-stranded, nos), as we believe our current methodology for determining payment rates for non-specified brachytherapy sources, as discussed in Section II.A.2.a.(2) of this proposed rule, is appropriate. Further, as discussed in additional detail in Section IV.B.5 of this proposed rule, we are proposing to eliminate our low volume Device-Intensive Procedure policy, for which HCPCS code 0308T has been the only procedure subject to this policy, and subsume the ratesetting for HCPCS code 0308T within our broader low volume APC proposal.

For this CY 2022 OPPS/ASC proposed rule, we evaluated certain New Technology APCs to determine if such APCs meet our low volume APC criteria. As previously mentioned, we are proposing to use the ''greatest of'' the geometric mean, the median, or the arithmetic mean at the procedure level for determining the low volume APC cost of the individual services assigned to New Technology APCs, rather than soliciting comment on which methodology to use. In claims data available for this CY 2022 OPPS/ASC proposed rule, there were 5 claims for APC 1562 (which reflects the assignment of new technology procedure HCPCS code C9751 (bronchoscopy with transbronchial ablation of lesions by microwave energy)) and 35 claims for APC 1908 (New Technology—Level 52 ($145,001–$160,000)) which reflects the assignment of new technology procedure CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy).

Given the low volume of claims for HCPCS code C9751, we propose for CY 2022 to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning HCPCS code C9751 to a New Technology APC. We found the greatest cost metric for HCPCS code C9751 to be $3,707.76. Therefore, for this proposed rule, we are proposing to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501–$4,000)) and we are proposing to designate APC 1562 (New Technology—Level 25 ($3,501–$4,000)) as a low volume APC with a proposed APC cost and payment rate of $3,750.50. Details regarding APC 1562 are shown in Table 36.

Additionally, given the low volume of claims for APC 1908 (New Technology—Level 52 ($145,001–$160,000)) which reflects the assignment of new technology procedure CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy), we propose for CY 2022 to calculate the geometric mean, arithmetic mean, and median costs to calculate an appropriate payment rate for purposes of assigning CPT code 0100T to a New Technology APC. We found the greatest cost metric for CPT code 0100T to be $155,412.90. Therefore, for this proposed rule, we are proposing to assign CPT code 0100T to APC 1908 (New Technology—Level 52 ($145,001–$160,000)) and we are proposing to designate APC 1908 (New Technology—Level 52 ($145,001–$160,000)) as a low volume APC with a proposed APC cost and payment rate of $152,500.50. Details regarding APC 1908 are shown in Table 36.

Further, for CY 2022, in addition to the 2 New Technology APCs we are proposing to designate as low volume APCs, we are also proposing to designate 4 clinical APCs and 5 brachytherapy APCs as low volume APCs under the OPPS. The 4 clinical APCs and 5 brachytherapy APCs meet our criteria of having fewer than 100 single claims in the claims year (CY 2019 for this CY 2022 OPPS/ASC proposed rule) and therefore, we propose that they would be subject to our new low volume APC policy, if finalized. Table 36 illustrates the APC geometric mean cost without the low volume APC designation, the median, arithmetic mean, and geometric mean cost using up to 4 years of claims data, as well as the statistical methodology we are proposing to use as the APC's cost for ratesetting purposes for CY 2022. As discussed in Section II.A.1.a of this proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, the 4 years of claims data are based on CY 2016 claims through CY 2019 claims.

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Table 36. Cost Statistics for Proposed Low Volume APCs for CY 2022

APC	APC Description	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	CY 2022 Proposed APC Cost
1562	New Technology – Level 25 ($3,501 - $4,000)	$2,692.69	$3,707.76	$3,085.64	$2,692.69	$3,750.50
1908	New Technology – Level 52 ($145,001 - $160,000)	$155,412.90	$150,363.60	$154,321.70	$148,778.00	$152,500.50
2632	Iodine I-125 sodium iodide	$26.04	$30.24	$38.52	$34.16	$38.52
2635	Brachytx, non-str, HA, P-103	$44.37	$34.04	$43.53	$36.72	$43.53
2636	Brachy linear, non-str, P-103	$30.59	$24.78	$50.16	$36.43	$50.16
2645	Brachytx, non-str, Gold-198	$280.90	$61.85	$588.31	$131.86	$588.31
2647	Brachytx, NS, Non-HDRIr-192	$275.13	$145.36	$196.38	$94.24	$196.38
5244	Level 4 Blood Product Exchange and Related Services	$31,015.17	$34,287.01	$39,444.97	$34,399.17	$39,444.97
5494	Level 4 Intraocular Procedures	$14,621.42	$16,155.58	$14,951.58	$11,490.23	$16,155.58
5495	Level 5 Intraocular Procedures	$17,414.85	$17,414.85	$17,414.85	$17,414.85	$17,414.85

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Based on the number of available claims from the standard ratesetting methodology used for ASC ratesetting purposes, for CY 2022, under the ASC payment system, we propose to designate 2 New Technology APCs, 3 clinical APCs, and 5 brachytherapy APCs as Low Volume APCs that meet our criteria of having fewer than 100 single claims in the claims year (CY 2019 for this CY 2022 OPPS/ASC proposed rule) and would be subject to our new Low Volume APC. Under our proposed Low Volume APC policy, the payment rates for these APCs would be set at the highest amount among the geometric mean, median, or arithmetic mean, calculated using up to four years of data, which in the case of these APCs, would be claims data from 2016 through 2019.

As discussed in Section II.A.1.a of this proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, the 4 years of claims data are based on claims from CY 2016 through CY 2019. We are soliciting comments from the public on our proposal to establish a Low Volume APC policy for clinical APCs, brachytherapy APCs, and New Technology APCs. This includes our criterion for designating an APC as a Low Volume APC, the use of the highest of the geometric mean, median, and arithmetic mean to determine the payment rate for clinical and brachytherapy APCs, as well as individual services assigned to New Technology APCs, and our use of claims data from CY 2016 through 2019 to calculate the geometric mean, median, and arithmetic mean for purposes of determining the CY 2022 payment rates for these APCs.

D. Comment Solicitation on Temporary Policies To Address the COVID–19 PHE

In response to the COVID–19 pandemic, CMS issued waivers and undertook emergency rulemaking to implement a number of temporary policies to address the pandemic, including policies to prevent spread of the infection and support diagnosis of COVID–19. Many of these flexibilities were available because certain statutory or regulatory provisions were waived. These waivers will expire at the conclusion of the PHE. We are seeking comment on the extent to which stakeholders utilized the flexibilities available under these waivers, as well as whether stakeholders believe certain of these temporary policies should be made permanent to the extent possible within our existing authority. Specifically, we are seeking comment on stakeholders' experience with hospital staff furnishing services remotely to beneficiaries in their homes through use of communications technology; providers furnishing services in which the direct supervision for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services requirement was met by the supervising practitioner being available through audio/video real-time communications technology; and the need for specific coding and payment to remain available under the OPPS for specimen collection for COVID–19.

1. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

Under the Physician Fee Schedule (PFS), Medicare makes payment to professionals and other suppliers for physicians' services, including certain diagnostic tests and preventive services. Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of Medicare telehealth services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunications technology. When furnished as Medicare telehealth services under section 1834(m), many of these services are still reported using codes that describe ''face-to-face'' services even though they are furnished using audio/video, real-time communications technology instead of in-person (82 FR 53006). Section 1834(m) of the Act specifies the types of health care professionals that can furnish and be paid by Medicare for telehealth services (referred to as distant site practitioners) and the types and locations of settings where a beneficiary can be located when receiving telehealth services (referred to as originating sites). In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare telehealth services list in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which we consider and review through the annual PFS rulemaking process. The regulation at § 410.78(a)(3) also defines the requirements for the interactive telecommunications systems that may be used to furnish Medicare telehealth services.

Due to the circumstances of the COVID–19 pandemic, particularly the need to maintain physical distance to avoid exposure to the virus, we anticipated that health care practitioners would develop new approaches to providing care using various forms of technology when they are not physically present with the patient. We have established several flexibilities to accommodate these changes in the delivery of care. For Medicare telehealth services, using waiver authority under section 1135(b)(8) of the Act in response to the PHE for the COVID–19 pandemic, we have removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for the COVID–19 pandemic. We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology during the PHE.

According to MedPAC's report, *Telehealth in Medicare after the Coronavirus Public Health Emergency,*[107] there were 8.4 million telehealth services paid under the PFS in April 2020, compared with 102,000 in February 2020. MedPAC also reported that during focus groups held in the summer of 2020, clinicians and beneficiaries supported continued access to telehealth visits with some combination of in-person visits. They cited benefits of telehealth, including improved access to care for those with physical impairments, increased convenience from not traveling to an office, and increased access to specialists outside of a local area. In their annual beneficiary survey, over 90 percent of respondents who had a telehealth visit reported being ''somewhat'' or ''very satisfied'' with their video or audio visit, and nearly two-thirds reported being ''very satisfied.''

Recently enacted legislation modified the circumstances under which Medicare makes payment for mental health services furnished via telehealth technology under the PFS following the PHE. Division CC, section 123 of the CAAremoved the geographic originating site restrictions and added the home of the individual as a permissible originating site for Medicare telehealth services when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder.[108]

[107] *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_ch14_sec.pdf?sfvrsn=0.*

[108] There is a longstanding statutory payment exclusion that prohibits Medicare payment for services that are not furnished within the United

Continued

This change correlates with a growing acceptance of the use of technology in the provision of mental health care. According to the Commonwealth Fund,[109] the provision of mental and behavioral health services via communications technology, in particular, has a robust evidence base and numerous studies have demonstrated its effectiveness across a range of modalities and mental health diagnoses (*e.g.,* depression, substance use disorders). Clinicians furnishing tele-psychiatry services at Massachusetts General Hospital Department of Psychiatry during the PHE observed several advantages of the virtual format for furnishing psychiatric services, noting that patients with psychiatric pathologies that interfere with their ability to leave home (*e.g.,* immobilizing depression, anxiety, agoraphobia, and/or time-consuming obsessive-compulsive rituals) were able to access care more consistently since eliminating the need to travel to a psychiatry clinic can increase privacy and therefore decrease stigma-related barriers to treatment, potentially bringing care to many more patients in need, as well as enhanced ease of scheduling, decreased rate of no-shows, increased understanding of family and home dynamics, and protection for patients and practitioners with underlying health conditions.[110]

These findings are consistent with our analysis of Medicare claims data that indicate that interactive communications technology for mental health care is likely to continue to be in broad use beyond the circumstances of the pandemic. According to our analysis of Medicare Part B claims data for services furnished via Medicare telehealth during the PHE, use of telehealth for many professional services spiked in utilization around April 2020 and diminished over time. In contrast, Medicare claims data suggest that for mental health services added to the Medicare Telehealth list both permanently and temporarily, subsequent to April 2020, the trend is toward maintaining a steady state of usage over time. Given this information, broad acceptance in the public and medical community, and the relatively stable Medicare utilization of mental health services during the COVID–19 pandemic, we believe use of interactive communication technology in furnishing mental health care is becoming an established part of medical practice, very likely to persist after the COVID–19 pandemic, and available across the country under the Medicare statute for the range of professionals furnishing mental health care and paid under the PFS.

In many cases, hospitals provide hospital outpatient mental health services (including behavioral health), education, and training services that are furnished by hospital-employed counselors or other licensed professionals. Examples of these services include psychoanalysis, psychotherapy, diabetes self-management training, and medical nutrition therapy. With few exceptions, the Medicare statute does not have a benefit category that would allow these types of professionals (for example, mental health counselors and registered nurses) to bill Medicare directly for their services. These services can, in many cases, be billed by providers such as hospitals under the OPPS or by physicians and other practitioners as services incident to their professional services under the PFS. We also note that while partial hospitalization services are paid under the OPPS, section 1861(ff)(3)(A) of the Act explicitly prohibits partial hospitalization services from being furnished in an individual's home or residential setting.

As we explained in the interim final rule with comment period published on May 8, 2020 titled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (the May 8th COVID–19 IFC) (85 FR 27550, 27563), outpatient mental health services, education, and training services require communication and interaction. We stated that facility staff can effectively furnish these services using telecommunication technology and, unlike many hospital services, the clinical staff and patient are not required to be in the same location to furnish them. We further explained that blanket waivers in effect during the COVID–19 PHE allow the hospital to consider the beneficiary's home, and any other temporary expansion location operated by the hospital during the COVID–19 PHE, to be a provider-based department (PBD) of the hospital, so long as the hospital can ensure the locations meet all of the conditions of participation, to the extent not waived. In light of the need for infection control and a desire for continuity of behavioral health care and treatment services, we recognized the ability of the hospital's clinical staff to continue to deliver these services even when they are not physically located in the hospital. Therefore, in the May 8th COVID–19 IFC (85 FR 27564), we made clear that when a hospital's clinical staff are furnishing hospital outpatient mental health services, education, and training services to a patient in the hospital (which can include the patient's home so long as it is provider-based to the hospital), and the patient is registered as an outpatient of the hospital, we will consider the requirements of the regulations at § 410.27(a)(1) to be met. We reminded readers that the physician supervision level for the vast majority of hospital outpatient therapeutic services is currently general supervision under § 410.27. This means a service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service.

In the May 8th COVID–19 IFC we emphasized that all services furnished by the hospital still require an order by a physician or qualified NPP and must be supervised by a physician or other NPP appropriate for supervising the service given their hospital admitting privileges, state licensing, and scope of practice, consistent with the requirements in § 410.27 (85 FR 27563). We noted that hospitals may bill for these services as if they were furnished in the hospital and consistent with any specific requirements for billing Medicare in general, including any relevant modifications in effect during the COVID–19 PHE. We also noted that when these services are provided by clinical staff of the physician or other practitioner and furnished incident to their professional services, and are not provided by staff of the hospital, the hospital would not bill for the services. We stated that in those circumstances, the physician or other practitioner should bill for such services incident to their own services and would be paid under the PFS.

Given that the widespread use of communications technology to furnish services during the PHE has illustrated acceptance within the medical community and among Medicare beneficiaries of the possibility of furnishing and receiving care through the use of that technology, we are interested in information on the role of hospital staff in providing care to beneficiaries remotely in their homes. During the PHE, hospital staff have had the flexibility to provide these kinds of services to beneficiaries in their homes through communications technology; however, this flexibility is tied to

States (see section 1862(a)(4) of the Act). This payment exclusion was not changed by the CAA.

[109] *https://www.commonwealthfund.org/blog/2020/using-telehealth-meet-mental-health-needs-during-covid-19-crisis.*

[110] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7347331/.*

waivers and other temporary policies that expire at the end of the PHE. In instances where a beneficiary may be receiving mental health services from a hospital clinical staff member who cannot bill Medicare independently for their professional service, the beneficiary would then need to physically travel to the hospital to continue receiving the services post-PHE. We are concerned that this could have a negative impact on access to care in areas where beneficiaries may only be able to access mental health services provided by hospital staff and, during the PHE, have become accustomed to receiving these services in their homes. We also note that the ability to receive mental health services in their homes may help expand access to care for beneficiaries who prefer additional privacy for the treatment of their condition.

We are concerned that, during the PHE, practice patterns may have shifted to support expanded virtual services. During the PHE, we have not required any claims-based modifier identifying specifically when a service is furnished by clinical staff of the hospital to a beneficiary in their home through communications technology, and therefore we are not able to gauge the magnitude of these practice pattern shifts. Therefore, we are seeking comment on the extent to which hospitals have been billing for mental health services provided to beneficiaries in their homes through communications technology during the PHE, and whether they would anticipate continuing demand for this model of care following the conclusion of the PHE. As described in preceding paragraphs, billing for Medicare telehealth services has increased dramatically during the PHE, particularly for mental health services. We are seeking comment on whether hospitals have experienced a similar increase during the PHE in utilization of mental health services provided by hospital staff to beneficiaries in their homes through communications technology. We are also seeking comment on whether there are changes commenters believe CMS should make to account for shifting patterns of practice that rely on communication technology to provide mental health services to beneficiaries in their homes.

2. Direct Supervision by Interactive Communications Technology

In the interim final rule with comment period titled ''Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency'' published on April 6, 2020 (the April 6th COVID–19 IFC) (85 FR 19230, 19246, 19286), we changed the regulation at 42 CFR 410.27(a)(1)(iv)(D) to provide that, during a Public Health Emergency as defined in § 400.200, the presence of the physician for purposes of the direct supervision requirement for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or practitioner. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(D) in the CY 2021 OPPS/ASC final rule with comment period to provide that this flexibility continues until the end of the PHE as defined in § 400.200 or December 31, 2021, whichever is later (85 FR 86113). We noted that the public comments we received, along with feedback we have received since the implementation of the policy in the April 6th COVID–19 IFC allowing for direct supervision through virtual presence (85 FR 19246) have convinced us that we need more information on the issues involved with direct supervision through virtual presence before implementing this policy permanently. We acknowledge that the additional time between the issuance of the CY 2021 OPPS/ASC final rule with comment period and the issuance of this proposed rule may have allowed providers to collection more information that could inform CMS' decision making and are therefore seeking additional comment on whether this policy should be adopted on a permanent basis. While we are not proposing to maintain this flexibility after the later of the end of the PHE or December 31, 2021, we are seeking comment on whether and to what extent hospitals have relied upon this flexibility during the PHE and whether providers expect this flexibility would be beneficial outside of the PHE. We are seeking comment on whether we should continue to allow direct supervision for these services to include presence of the supervising practitioner via two-way, audio/video communication technology permanently, or for some period of time after the conclusion of the PHE or beyond December 31, 2021, to facilitate a gradual sunset of the policy. We are also seeking comment on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE. Finally, if this policy is made permanent, we are seeking comment on whether a service-level modifier should be required to identify when the requirements for direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services were met using audio/video real-time communications technology.

3. Payment for COVID–19 Specimen Collection in Hospital Outpatient Departments

Also in the May 8th COVID–19 IFC, we created a new E/M code to support COVID–19 testing during the PHE: HCPCS code C9803 (*Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars–cov–2) (coronavirus disease [covid–19]), any specimen source*) (85 FR 27604). In our review of available HCPCS and CPT codes for the May 8th COVID–19 IFC, we did not identify a code that explicitly described the exact services of symptom assessment and specimen collection that HOPDs were undertaking to facilitate widespread testing for COVID–19. As stated in the May 8th COVID–19 IFC, we believed that HCPCS code C9803 was necessary to meet the resource requirements for HOPDs to provide extensive testing for the duration of the COVID–19 PHE. This code was created only to meet the need of the COVID–19 PHE and we stated that we expected to retire this code at the conclusion of the COVID–19 PHE (85 FR 27605).

We assigned HCPCS code C9803 to APC 5731—Level 1 Minor Procedures effective March 1, 2020 for the duration of the COVID–19 PHE. In accordance with Section 1833(t)(2)(B) of the Act, APC 5731—Level 1 Minor Procedures contains services similar to HCPCS code C9803. APC 5731—Level 1 Minor Procedures has a payment rate of $24.67 for CY 2021. HCPCS code C9803 was also assigned a status indicator of ''Q1.'' The Q1 status indicator indicates that the OPPS will package services billed under HCPCS code C9803 when billed with a separately payable primary service in the same encounter. When HCPCS code C9803 is billed without another separately payable primary service, we will make separate payment for the service under the OPPS. The OPPS also makes separate payment for HCPCS code C9803 when it is billed with a clinical diagnostic laboratory test with a status indicator of ''A'' on Addendum B of the OPPS.

We are soliciting public comments on whether we should keep HCPCS code C9803 active beyond the conclusion of the COVID–19 PHE and whether we should extend or make permanent the OPPS payment associated with specimen collection for COVID–19 tests after the COVID–19 PHE ends, including why commenters believe it would be necessary to continue to provide OPPS payment for this service, as well as how long commenters believe payment should be extended for this code.

E. Use of CY 2019 Claims Data for CY 2022 OPPS and ASC Payment System Ratesetting Due to the PHE

As described in section I.A. of this proposed rule with comment period, section 1833(t) of the Social Security Act requires the Secretary 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 not less often than annually and to 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.

In updating the OPPS payment rates and system for each rulemaking cycle we primarily use two sources of information: The outpatient Medicare claims data and HCRIS cost report data. The claims data source is the Outpatient Standard Analytic File, which includes final action Medicare outpatient claims for services furnished in a given calendar year. For the OPPS ratesetting process, our goal is to use the best available data for ratesetting so that we can accurately estimate the costs associated with furnishing outpatient services, and thus set appropriate payment rates. Ordinarily, the best available claims data is the set of data from 2 years prior to the calendar year that is the subject of rulemaking. For CY 2022 OPPS/ASC proposed rule ratesetting, this typically would have been the set of CY 2020 calendar year outpatient claims data processed through December 31, 2020. The cost report data source is typically the Medicare hospital cost report data files from the most recently available quarterly HCRIS file as we begin the ratesetting process. For example, ordinarily, the best available cost report data used in developing the OPPS relative weights would be from cost reports beginning 3 fiscal years prior to the year that is the subject of the rulemaking. For CY 2022 OPPS ratesetting, under ordinary circumstances, that would be cost report data from HCRIS extracted in December 2020, which would contain many cost reports ending in FY 2020 based on each hospital's cost reporting period.

As discussed in section I.F. of the FY 2022 IPPS/LTCH proposed rule, there are a number of issues related to the use of the standard hospital data we would otherwise use for purposes of CY 2022 ratesetting because data from the applicable time period would include the effects of the COVID–19 PHE (86 FR 25086 through 25090). Even though the specific data elements might be slightly different between the inpatient and outpatient hospital settings, the same questions and challenges exist for hospital data from CY/FY 2020. Some of the issues are focused on the source data and the degree to which the utilization of services and cost patterns found in them are affected by the PHE. Other issues are more prospective in nature and concern whether hospital claims data from this time period might be consistent with our expectations for the prospective year, particularly in a changing environment with regards to COVID–19 vaccinations and treatment.

In the FY 2022 IPPS proposed rule, we proposed to use FY 2019 data for FY 2022 IPPS ratesetting based on our determination that the FY 2019 data would be more representative of FY 2022 inpatient hospital experience than the FY 2020 data (86 FR 25089). We note that there are a number of policies that apply and interact across the IPPS and OPPS, in part because they both concern services furnished in the hospital setting. We have noted in annual rulemaking in regards to adopting the fiscal year IPPS wage index into the OPPS, the ''inseparable, subordinate status of the HOPD within the hospital overall'' (85 FR 85908). It is in this context where inpatient and outpatient hospital departments are inherently connected to each other, as parts of the broader hospital setting overall, that we have identified many of the same reasons to use 2019 data for 2022 ratesetting as discussed in the FY 2022 IPPS proposed rule.

We note that we observe a number of changes, likely as a result of the PHE, in the CY 2020 OPPS claims data that we would ordinarily use for ratesetting. The most significant difference compared to prior years is the decrease in the overall volume of outpatient hospital claims—with approximately 20 percent fewer claims usable for ratesetting purposes when compared to the prior year. In addition, this decrease in outpatient claims volume applied to a majority of the clinical APCs in the OPPS.

In some cases, we saw broad changes as a result of the PHE, including in the APCs for hospital emergency department and clinic visits. Among those APCs, the decrease in volume was approximately 30 percent—some of which may be related to changing practice patterns during the PHE. For example, we see a significant increase in the use of the HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims, with the approximately 35,000 services billed in the CY 2019 OPPS claims increasing to 1.8 million services in the CY 2020 OPPS claims. This example highlights two types of differences we see in the CY 2020 set of claims when comparing to more typical claims data. One difference is likely due to the degree to which elective procedures/services were not performed as often during the PHE. The other difference is the result of site of service changes due to flexibilities available during the PHE.

In other cases, we saw changes in the claims data that were associated with specific services that were furnished more frequently during the PHE. For example, two notable exceptions to this decrease in claims volume between CY 2019 and CY 2020 are for APC 5731 (Level 1 Minor Procedures) and APC 5801 (Ventilation Initiation and Management). In the case of APC 5731, HCPCS code C9803 was made effective for services furnished on or after March 1, 2020 through the interim final rule with comment period titled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (85 FR 27602 through 27605) to describe a COVID–19 Specimen collection. In the CY 2020 claims, HCPCS C9803 has 1,023,957 single claims available for cost modeling, representing approximately 93% of claims used to model the APC cost. While in some cases this would be appropriate in establishing the APC cost, we generally would not expect the same volume of the procedure in the CY 2022 OPPS because we anticipate that specimen collection for COVID–19 testing will be significantly lower than it was in CY 2020. Similarly, the estimated increase in the geometric mean cost of APC 5801 based on the CY 2020 claims data may not be predictive of CY 2022 costs for APC 5801 if there is less use of this service in CY 2022 than in CY 2020.

As a result of a number of COVID–19 PHE-related factors, including the

changes in services potentially related to the COVID–19 PHE, the significant decrease in volume suggesting that patients may have been deferring elective care during CY 2020, the changes in APC relative weights for services, and the increasing number of Medicare beneficiaries vaccinated against COVID–19, we believe that CY 2020 data are not the best overall approximation of expected outpatient hospital services in CY 2022. Instead we believe that CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, are a better approximation of expected CY 2022 hospital outpatient services.

We analyzed the extent the decision to use CY 2019 or CY 2020 claims data as the basis for ratesetting differentially impacts the CY 2022 OPPS rates. To do this, we estimated the difference in case-mix under the CY 2019-based weights and the CY 2020-based weights if the CY 2022 outpatient experience ended up being the reverse of the assumption made when calculating that set of relative weights. In other words, we compared estimated case-mix calculated under four different scenarios. For the CY 2019-based weights, we calculated the case-mix using claims from the CY 2019-based claims extract as an approximation of the actual CY 2022 experience (Scenario A), and using claims from the CY 2020 based claims extract as an approximation of the actual CY 2022 experience (Scenario B). For the CY 2020-based weights, we calculated the case-mix using claims from the CY 2020 claims based extract as an approximation of the actual CY 2022 outpatient experience (Scenario C), and using claims from the CY 2019 claims based extract as an approximation of the actual CY 2022 experience (Scenario D). The results are shown in the following table 37.

Table 37: Estimated Impact of Claims Based Assumptions for CY 2022 Outpatient Experience

Scenario	Assumed CY 2022 Experience for Relative Weights	Actual CY 2022 Experience	Case-mix	Assumption Matched Experience	Percent change in case-mix if Mismatch between Assumption and Actual Experience
A	CY 2019	CY 2019	4.620	Yes	
B	CY 2019	CY 2020	5.056	No	0.10%
C	CY 2020	CY 2020	5.051	Yes	
D	CY 2020	CY 2019	4.600	No	-0.44%

In Scenario A and Scenario C, there is no differential impact as a result of a less accurate assumption made when the OPPS relative weights were calculated: The CY 2022 outpatient experience matches the assumption made when the OPPS relative weights were calculated. In Scenario B and Scenario D, the actual experience is the reverse of the assumption used when the OPPS relative weights were calculated.

In Scenario B, when the CY 2019-based weights were used, but the CY 2022 outpatient experience turns out to be more similar to CY 2020 claims data, the less accurate assumption slightly affects the calculated case-mix, by 0.1 percent. This can be seen by comparing the modeled case mix under Scenario B (5.056) with the modeled case-mix under Scenario C (5.051). In other words, if we use the CY 2019-based weights and CY 2022 outpatient experience turns out to be more similar to the CY 2020 data, then the modeled case-mix is slightly lower than if we had accurately used the CY 2020-based weights. This suggests that, while there is some impact from using the CY 2019 data if CY 2022 outpatient service utilization ends up being more similar to CY 2020 utilization, that impact would be limited.

In Scenario D, where the CY 2020-based weights were used, but the CY 2022 outpatient experience turns out to be more similar to CY 2019 claims data, this inaccurate assumption has a somewhat more significant effect. In this case, the modeled case-mix is −0.44 percent lower than it would be if we had correctly assumed that CY 2022 outpatient services utilization would be more like CY 2019 than CY 2020. This can be seen by comparing the modeled case-mix under Scenario D (4.600) to the modeled case-mix under Scenario A (4.620). In other words, if we use the CY 2020-based weights and the CY 2022 outpatient experience turns out to be more similar to CY 2019 data, the modeled case-mix is −0.44 percent lower than if we had used the CY 2019-based weights.

In addition to our expectation that CY 2019 is a more likely approximation of the CY 2022 outpatient experience for the reasons discussed earlier, the previous analysis indicates that the differential effect of making an incorrect assumption about which year's data to use to set the CY 2022 OPPS relative weights is more limited if the CY 2019-based weights are used than it is if the CY 2020-based weights are used. While CY 2022 outpatient hospital services data is unlikely to look exactly like either CY 2019 data or CY 2020 data, we believe that it will be more similar to a standard year (not having the effects of the PHE) as pandemic-related issues decline and more of the U.S. population is vaccinated against COVID–19. Since the update provided in the FY 2022 IPPS final rule, continued progress has been made in vaccinating the U.S. population, with approximately 320 million doses administered as of July 1, 2021, as reported to the Centers for Disease Control (CDC) *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html*.

Consistent with the proposal to use CY 2019 claims data in establishing the CY 2022 OPPS rates, we are also proposing to use cost report data from

the same set of cost reports we originally used in final rule 2021 OPPS ratesetting, where we ordinarily would have used the most updated available cost reports available in HCRIS in determining the proposed CY 2022 OPPS APC relative weights (as discussed in greater detail in section II.E. of this proposed rule). As discussed previously, if we were to proceed with the standard ratesetting process of using updated cost reports, we would have used approximately 1,000 cost reports with the fiscal year ending in CY 2020 based on each hospital's cost reporting period. We note that Medicare outpatient claims data and cost report data from the HCRIS file are examples of data sources for which we discuss the proposed use of CY 2019 data for CY 2022 OPPS ratesetting. While we are generally using CY 2019 claims data and the data components related to it in establishing the CY 2022 OPPS, we note in this rule the specific cases where we are using updated information, such as the ASP data used in determining drug packaging status discussed in section V. of this proposed rule with comment period.

We also considered the alternative of continuing with our standard process of using the most updated claims and cost report data available. To facilitate comment on this alternative proposal for CY 2022, we are making available the cost statistics and addenda utilizing the CY 2020 data we would ordinarily have provided in conjunction with this proposed rule. We are providing a file comparing the budget neutrality and certain other ratesetting adjustments calculated under our proposal with those adjustments calculated under this alternative approach. Finally, we are making available other proposed rule supporting data files based on the use of the CY 2020 data that we ordinarily would have provided, including: The OPPS Impact File, cost statistics files, addenda, and budget neutrality factors. We refer the reader to the CMS website for this proposed rule for more information on where these supplemental files may be found.

F. Proposal To Provide Separate Payment in CY 2022 for the Device Category, Drugs, and Biologicals With Transitional Pass-Through Payment Status Expiring Between December 31, 2021 and September 30, 2022

In the CY 2021 OPPS/ASC final rule (85 FR 86012 through 86013), we discussed the public comments we received in response to the comment solicitation we included in the CY 2021 OPPS/ASC proposed rule regarding whether we should utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for some period of time after pass-through status ends for devices with expiring pass-through status in order to account for the period of time that utilization for the devices was reduced due to the PHE.[111] Although we only solicited comments on use of our equitable adjustment authority to pay separately for devices with pass-through status during the PHE, we received public comments both suggesting that drugs, biologicals, and biosimilar biological products with pass-through status during the same time period should also be subject to an adjustment to extend the pass-through period for those products, but also pointing out that most of these products continue to be separately paid after their pass-through status expires, and therefore, it would be unnecessary to utilize the equitable adjustment authority to ''extend'' pass-through status for these products.

As discussed elsewhere in section X.E. of this proposed rule and section I.F of the FY 2022 IPPS/LTCH proposed rule (86 FR 25211–25212), our goal is to use the best available data for ratesetting. Ordinarily, the best available claims data is the set of data from 2 years prior to the calendar year that is the subject of rulemaking, and accordingly, we would have used claims data from CY 2020 for calculating proposed rates for this CY 2022 OPPS/ASC proposed rule. As noted in section X.E., however, we are proposing to use CY 2019 claims data in establishing the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in the final rule for 2021 OPPS ratesetting. We recognize that due to the effects of the PHE, the CY 2020 claims data may not be the best available data for ratesetting, including for purposes of ratesetting for devices, drugs, and biologicals for which pass-through status expires between December 31, 2021 and September 30, 2022.

For this reason, and after consideration of the public comments we received in response to the comment solicitation included in the CY 2021 OPPS/ASC proposed rule (85 FR 48862), we propose a one-time equitable adjustment under section 1833(t)(2)(E) to continue separate payment for the remainder of CY 2022 for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022. We have consistently explained that transitional pass-through payment for drugs, biologicals, and devices is intended as an interim measure to allow for adequate payment of certain new technology while we collect the necessary data to incorporate the costs for these items into the procedure APC rate (66 FR 55861). We believe an equitable adjustment to continue separate payment for devices, drugs, and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022 is necessary to ensure that we have full claims data from CY 2021 with which to set payment rates beginning in CY 2023. We also believe it is necessary to pay separately for these products in CY 2022 in a manner that mimics continued pass-through status, rather than having to set rates and make APC assignments and packaging decisions for these products for CY 2022 based on data from CY 2020, which we do not believe is the best available data for this purpose.

For those drugs, biologicals and the device for which payment would be packaged following expiration of their pass-through status, we believe providing separate payment for up to a full year in CY 2022 is warranted to ensure there is a full year of data for ratesetting, including to ensure appropriate APC assignments for the services with which these products are billed. For drugs and biologicals that would generally remain separately payable after their pass-through status expires, we believe providing separate payment for up to a full year in CY 2022 is necessary to ensure that these drugs and biologicals would, in fact, be separately payable when their pass-through status expires, including to ensure that their payment would be packaged if the drug's cost is below the per-day packaging threshold. Specifically, for threshold packaged drugs and biologicals, CMS requires current, appropriate data to determine whether the drug should be packaged and then to determine the impact of that packaging on the associated service rates. We also believe separate payment in CY 2022 is necessary to ensure we have sufficient data in the event payment for the drug is packaged with payment for a primary C–APC service. Finally, consistent with our goal of ensuring that the equitable adjustment

[111] On January 31, 2020, HHS Secretary Azar determined that a PHE exists retroactive to January 27, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d) in response to COVID–19, and on April 21, 2020 Secretary Azar renewed, effective April 26, 2020, and again effective July 25, 2020, the determination that a PHE exists. On March 13, 2020, the President of the United States declared that the COVID–19 outbreak in the U.S. constitutes a national emergency, retroactive to March 1, 2020.

to provide separate payment for drugs and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022 mimics pass-through payment to the extent possible, we propose that separately payable drugs and biologicals that are eligible for this adjustment would not be paid the proposed reduced amount of ASP minus 22.5 percent when they are acquired under the 340B program, and would generally continue to be paid ASP plus 6 percent for the duration of the time period during which the adjustment applies.

Under our proposal, the device category, drugs, and biologicals that would be affected are as follows. One device category, HCPCS code C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads), would receive adjusted payment equivalent to an additional four quarters of device pass-through status. There are 27 drugs and biologicals whose pass-through payment status expires between December 31, 2021 and September 30, 2022. Based on the CY 2020 data, payment for three of the 27 drugs and biologicals would otherwise be packaged after the expiration of their pass-through status. The remaining 24 drugs and biologicals would be paid separately and would otherwise receive reduced payment at the proposed rate of ASP minus 22.5 percent when they are acquired under the 340B program.

There are currently six drugs and one device category whose pass-through payment status will expire on December 31, 2021, nine drugs and three biologicals whose pass-through status will expire on March 31, 2022, seven drugs whose pass-through status will expire on June 30, 2022, and two drugs whose pass-through payment status will expire on September 30, 2022. Because pass-through status can expire at the end of a quarter, the proposed adjusted payment would be made for between one and four quarters, depending on when the pass-through period expires for the device category, drug, or biological. In particular, separate payment would be made a full year for the device category and 6 drugs for which pass-through status will expire on December 31, 2021, three quarters for the 12 drugs and biologicals for which pass-through status will expire on March 31, 2022, two quarters for the 7 drugs for which pass-through status will expire on June 30, 2022, and one quarter for the 2 drugs for which pass-through status will expire on September 30, 2022.

Table 38 lists pass-through drugs, biologicals and the device category that we propose would receive adjusted separate payment, their pass-through payment period effective dates and end dates, as well as the number of quarters of separate payment equivalent to an extension of pass-through status that we propose each drug or device category would receive.

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TABLE 38: DEVICE CATEGORY, DRUGS, AND BIOLOGICALS WITH EXPIRING PASS-THROUGH STATUS THAT WOULD RECEIVE SEPARATE PAYMENT FOR ONE TO FOUR QUARTERS IN CY 2022

HCPCS Code	Long Descriptor	Pass-Through Status Effective Date	Pass-Through Status Expiration Date	Proposed Adjustment Equivalent to an Extension of Pass-through Status (number of quarters)
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads)	01/01/2019	12/31/2021	4
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	01/01/2019	12/31/2021	4
J0222	Injection, Patisiran, 0.1 mg	01/01/2019	12/31/2021	4
J0291	Injection, plazomicin, 5 mg	01/01/2019	12/31/2021	4
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	01/01/2019	12/31/2021	4
J2798	Injection, risperidone, (perseris), 0.5 mg	01/01/2019	12/31/2021	4
J9204	Injection, mogamulizumab-kpkc, 1 mg	01/01/2019	12/31/2021	4
J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	04/01/2019	03/31/2022	3
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	04/01/2019	03/31/2022	3
J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	01/01/2020	03/31/2022	3
J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	04/01/2019	03/31/2022	3
J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	04/01/2019	03/31/2022	3
J3245	Injection, tildrakizumab, 1 mg	04/01/2019	03/31/2022	3
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	04/01/2019	03/31/2022	3
J9119	Injection, cemiplimab-rwlc, 1 mg	04/01/2019	03/31/2022	3
J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	04/01/2019	03/31/2022	3

HCPCS Code	Long Descriptor	Pass-Through Status Effective Date	Pass-Through Status Expiration Date	Proposed Adjustment Equivalent to an Extension of Pass-through Status (number of quarters)
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	04/01/2019	03/31/2022	3
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	04/01/2019	03/31/2022	3
Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	04/01/2019	03/31/2022	3
C9047	Injection, caplacizumab-yhdp, 1 mg	07/01/2019	06/30/2022	2
J0121	Injection, omadacycline, 1 mg	07/01/2019	06/30/2022	2
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	07/01/2019	06/30/2022	2
J1303	Injection, ravulizumab-cwvz, 10 mg	07/01/2019	06/30/2022	2
J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	07/01/2019	06/30/2022	2
J9210	Injection, emapalumab-lzsg, 1 mg	07/01/2019	06/30/2022	2
J9269	Injection, tagraxofusp-erzs, 10 micrograms	07/01/2019	06/30/2022	2
J3111	Injection, romosozumab-aqqg, 1 mg	10/01/2019	09/30/2022	1
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	10/01/2019	09/30/2022	1

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We are soliciting comments on our proposal to utilize our equitable adjustment authority to pay separately for the remainder of CY 2022 for the device category, drugs and biologicals with pass-through status that expires between December 31, 2021 and September 30, 2022.

XI. Proposed CY 2022 OPPS Payment Status and Comment Indicators

A. Proposed CY 2022 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.

For CY 2022, we are not proposing to make any changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2021 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*.

We are requesting public comments on the proposed definitions of the OPPS status indicators for CY 2022.

The complete list of the proposed payment status indicators and their definitions that would apply for CY 2022 is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

The proposed CY 2022 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

B. Proposed CY 2022 Comment Indicator Definitions

In this proposed rule, we propose to use four comment indicators for the CY 2022 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2021 and we propose to continue their use in CY 2022. The proposed CY 2022 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.

The definitions of the proposed OPPS comment indicators for CY 2022 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

We believe that the existing CY 2021 definitions of the OPPS comment indicators continue to be appropriate for CY 2022. Therefore, we propose to use those definitions without modification for CY 2022.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2021 report.

A. Proposed OPPS Payment Rates Update

The March 2021 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress update Medicare OPPS payment rates by 2 percent, with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' We refer readers to the March 2021 report for a complete discussion of these recommendations.[112] We appreciate MedPAC's recommendations, but as MedPAC acknowledged in its March 2021 report, the Congress would need to change current law to enable us to implement its recommendations.

B. Proposed ASC Conversion Factor Update

In the March 2021 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC found that, based on its analysis of indicators of payment adequacy, the number of ASCs had increased, beneficiaries' use of ASCs had increased, and ASC access to capital has been adequate.[113] As a result, for CY 2022, MedPAC stated that payments to ASCs are adequate and recommended that in the absence of cost report data no payment update should be given for CY 2022 (that is, the update factor would be zero percent).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59079), we adopted a policy, which we codified at 42 CFR 416.171(a)(2), to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for complete details regarding our policy to use the productivity-adjusted hospital market basket update for the ASC payment system for CY 2019 through CY 2023. Therefore, consistent with our policy for the ASC payment system, as discussed in section XIII.G. of this proposed rule, we propose to apply a 2.3 percent productivity-adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2022 ASC payment amounts.

C. ASC Cost Data

In the March 2021 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, and that CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or an ASC specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program but should make cost reporting a condition of ASC participation in the Medicare program.[114]

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we are not proposing any cost reporting requirements for ASCs in this CY 2022 OPPS/ASC proposed rule, we are interested in public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. Such cost data would be beneficial in establishing an ASC-specific market basket index for updating payment rates under the ASC payment system.

The full March 2021 MedPAC Report to Congress can be downloaded from MedPAC's website at: *http://www.medpac.gov*.

XIII. 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, 2018, 2019, 2020, and 2021 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; 82 FR 59401 through 59424; 83 FR 59028 through

[112] Medicare Payment Advisory Committee. March 2021 Report to the Congress. Chapter 3: Hospital Inpatient and outpatient services, pp.81–82. Available at: *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf?sfvrsn=0*.

[113] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.147. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0*.

[114] Medicare Payment Advisory Committee. March 2021 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.157. Available at: *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf?sfvrsn=0*.

59080; 84 FR 61370 through 61410, and 85 FR 86121 through 86179, respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under §§ 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, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15.

In previous years, we identified 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).

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at 42 CFR 416.164(b), we 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; (5) certain radiology services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs that function as a supply when used in a surgical procedure. 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 paid for 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 American Medical Association (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 is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

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, 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 historically 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 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.

As we noted in the August 7, 2007 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.

However, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), after consideration of public comments received in response to the CY 2019 OPPS/ASC proposed rule and earlier OPPS/ASC rulemaking cycles, we revised our definition of a surgical procedure under the ASC payment system. In that final rule, we defined 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 AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), 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 determined met the general standards established in previous years for addition to the CPL. These criteria included that a procedure is not expected to pose a significant risk to beneficiary safety when performed in an ASC, that standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and that the procedure is separately

paid under the OPPS. In CY 2021, we revised the definition of covered surgical procedures to surgical procedures specified by the Secretary that are separately paid under the OPPS, are not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, are not only able to be reported using a CPT unlisted surgical procedure code, and are not otherwise excluded under § 411.15 (85 FR 86153).

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. 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, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify and track drugs, devices, 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. We refer to these codes as new and revised in this CY 2022 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we are proposing to solicit public comments in this proposed rule (and respond to those comments in the CY 2022 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2022 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2023 OPPS/ASC final rule with comment period).

2. April 2021 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For the April 2021 update, there was one new CPT code and there were 11 new Level II HCPCS codes. In the April 2021 ASC quarterly update (Transmittal 10702, CR 12183, dated April 1, 2021), we added 11 new Level II HCPCS codes to the list of ASC covered surgical procedures and the list of covered ancillary services. Table 39 below lists the new Level II HCPCS codes that were implemented April 1, 2021, along with their proposed payment indicators for CY 2022. The proposed comment indicators, payment indicators and payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule. The list of proposed ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective April 1, 2021 are assigned to comment indicator ''NP'' in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. Also, the list of proposed comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

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TABLE 39.—NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 PI
A9592	Copper cu-64, dotatate, diagnostic, 1 millicurie	NP	K2
C9074*	Injection, lumasiran, 0.5 mg	NP	K2
C9776	Intraoperative near-infrared fluorescence imaging of major extra-hepatic bile duct(s) (e.g., cystic duct, common bile duct and common hepatic duct) with intravenous administration of indocyanine green (icg) (list separately in addition to code for primary procedure)	NP	N1
C9777	Esophageal mucosal integrity testing by electrical impedance, transoral (list separately in addition to code for primary procedure)	NP	N1
J1427	Injection, viltolarsen, 10 mg	NP	K2
J1554	Injection, immune globulin (asceniv), 500 mg	NP	K2
J7402	Mometasone furoate sinus implant, (sinuva), 10 micrograms	NP	K2
J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	NP	K2
J9349	Injection, tafasitamab-cxix, 2 mg	NP	K2

*HCPCS code C9074, which was effective April 1, 2021, was deleted June 30, 2021 and replaced with HCPCS code J0224 (Injection, lumasiran, 0.5mg) effective July 1, 2021.

We are inviting public comments on these proposed payment indicators for the new HCPCS codes that were recognized as ASC covered surgical procedures and ancillary services in April 2021 through the quarterly update CRs, as listed in Table 39 above. We are proposing to finalize their payment indicators in the CY 2022 OPPS/ASC final rule with comment period.

3. July 2021 HCPCS Codes for Which We Are Soliciting Public Comments in This Proposed Rule

In the July 2021 ASC quarterly update (Transmittal 10858, Change Request 12341, dated June 25, 2021), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 40 below lists the new HCPCS codes that are effective July 1, 2021. The proposed payment indicators and payment rates for these codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of proposed ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective July 1, 2021 are assigned comment indicator ''NP'' in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on those assignments. The list of proposed comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

TABLE 40.—NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 PI
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	NP	K2
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	NP	K2
C1761	Catheter, transluminal intravascular lithotripsy, coronary	NP	J7
C9075	Injection, casimersen, 10 mg	NP	K2
C9076	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	NP	K2
C9077	Injection, cabotegravir and rilpivirine, 2mg/3mg	NP	K2
C9078	Injection, trilaciclib, 1mg	NP	K2
C9079	Injection, evinacumab-dgnb, 5mg	NP	K2
C9080	Injection, melphalan flufenamide hydrochloride, 1 mg	NP	K2
C9778	Colpopexy, vaginal; minimally invasive extra-peritoneal approach (sacrospinous)	NP	G2
J0224*	Injection, lumasiran, 0.5mg	NP	K2
J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 1 mg	NP	K2
J7168	Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity	NP	K2
J9348	Injection, naxitamab-gqgk, 1 mg	NP	K2
J9353	Injection, margetuximab-cmkb, 5 mg	NP	K2
Q4201	Matrion 1 sq cm	NP	N1
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	NP	K2

*HCPCS code C9074, which was effective April 1, 2021, was deleted June 30, 2021 and replaced with HCPCS code J0224 (Injection, lumasiran, 0.5mg) effective July 1, 2021.

In addition, through the July 2021 quarterly update CR, we added 11 new Category III CPT codes to the list of ASC covered ancillary services, effective July 1, 2021. This code is listed in Table 41 below, along with the proposed comment indicator and payment indicator. The CY 2022 proposed payment rate for these new Category III CPT codes can be found in Addendum BB. As noted above, the lists of proposed payment indicators and comment indicators used under the ASC payment system are included in Addenda DD1 and DD2, respectively, of this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

TABLE 41.—NEW CATEGORY III CPT CODE FOR COVERED ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2021

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 PI
0493T	Contact near-infrared spectroscopy studies of lower extremity wounds (eg, for oxyhemoglobin measurement)	CH	N1
0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	NP	J8
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	NP	J8
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	NP	Z2
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	NP	N1
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	NP	J8
0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	NP	J8

CY 2021 HCPCS Code	CY 2021 Long Descriptor	Proposed CY 2022 CI	Proposed CY 2022 PI
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	NP	J8
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	NP	J8
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging	NP	G2
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)	NP	N1

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We are inviting public comments on the proposed comment indicators and payment indicators for the new Level II HCPCS codes newly recognized as ASC covered surgical procedures and covered ancillary services and the new Category III CPT codes for covered ancillary services beginning in July 2021 through the quarterly update CRs, as listed in Tables 39, 40, and 41 above. We are proposing to finalize the proposed payment indicators in the CY 2022 OPPS/ASC final rule with comment period.

4. October 2021 HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2022 OPPS/ASC Final Rule With Comment Period

For CY 2022, consistent with our established policy, we are proposing that the Level II HCPCS codes that will be effective October 1, 2021 would be flagged with comment indicator ''NI'' in Addendum B to the CY 2022 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2022. We will invite public comments in the CY 2022 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

5. January 2022 HCPCS Codes

a. Level II HCPCS Codes for Which We Will Be Soliciting Public Comments in the CY 2022 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 January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the January 2022 ASC Update CR, and included on the CMS HCPCS website and in the CY 2022 OPPS/ASC final rule with comment period.

In addition, for CY 2022, we propose to continue our established policy of assigning comment indicator ''NI'' in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2022 to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2022 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2023 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Are Soliciting Public Comments in This Proposed Rule

For new and revised CPT codes effective January 1, 2022 that were received in time to be included in this proposed rule, we are proposing the appropriate payment indicator assignments, and soliciting public comments on the payment assignments. We will accept comments and finalize the payment indicators in the CY 2022 OPPS/ASC final rule with comment period. For those new/revised CPT codes that are received too late for inclusion in this OPPS/ASC proposed rule, we may either make interim final assignments in the CY 2022 OPPS/ASC final rule with comment period or 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.

For the CY 2022 ASC update, the new and revised Category I and III CPT codes that will be effective on January 1, 2022 can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website). The CPT 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 the current calendar year and that comments will be accepted on the proposed payment indicator. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we include the 5-digit placeholder codes and their long descriptors for the new and revised CY 2022 CPT codes in Addendum O to this proposed rule (which is available via the internet on

the CMS website) so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O to this proposed rule, specifically under the column labeled ''CY 2021 OPPS/ASC Proposed Rule 5-Digit Placeholder Code.'' The final CPT code numbers will be included in the CY 2022 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2022 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2022. Because these codes are listed in Addenda AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We are also proposing to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2022 OPPS/ASC final rule with comment period. The proposed payment indicator and comment indicator for these codes can be found in Addendum AA and BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new CPT codes that will be effective January 1, 2022 are assigned to comment indicator ''NP'' in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on their interim ASC payment assignments. Also, the list of comment indicators and definitions used under the ASC can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

Finally, in Table 42 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 ASC payment system.

TABLE 42.—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2021	HCPCS (CPT and Level II codes)	April 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
July 2021	HCPCS (CPT and Level II codes)	July 1, 2021	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
October 2021	HCPCS (CPT and Level II codes)	October 1, 2021	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period
January 2022	CPT Codes	January 1, 2022	CY 2022 OPPS/ASC proposed rule	CY 2022 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2022	CY 2022 OPPS/ASC final rule with comment period	CY 2023 OPPS/ASC final rule with comment period

C. Proposed 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 Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished 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

with 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 to include all covered surgical procedures 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 non office-based, after taking into account updated volume and utilization data.

(2) Proposed Changes for CY 2022 to Covered Surgical Procedures Designated as Office-Based

In developing this CY 2022 OPPS/ASC proposed rule, 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 (described in detail in section XIII.C.1.d), including their potential designation as office-based. Historically, we would also review the most recent claims volume and utilization data (CY 2020 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2020 of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight), as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86131 through 86139). However, as discussed in Section II.A.1.a of this proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, we are not proposing to review the most recent claims volume and utilization data from CY 2020 claims and instead we are proposing not to assign permanent office-based designations for CY 2022 to any covered surgical procedure currently assigned a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight).

Similarly, we are also proposing not to use the most recent claims volume and utilization data and other information for procedures designated as temporarily office-based and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3'' or ''R2,'' as shown in Table 56 and Table 57 in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86136 through 86137). Instead, we propose to continue to designate these procedures, shown in Table 43, as temporarily office-based for CY 2022. The procedures we propose to designate as temporarily office-based for CY 2022 are identified with an asterisk in Addendum AA to this proposed rule with comment period (which is available via the internet on the CMS website).

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TABLE 43: PROPOSED CY 2022 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2021 OPPS/ASC FINAL RULE

CY 2022 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2021 ASC Payment Indicator	Proposed CY 2022 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	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 (report medication separately)	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2	R2*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2022 PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2022 PFS proposed rule.

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As discussed in the August 2, 2007 revised ASC payment system final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures would be permanently assigned to the list of office-based

procedures. In the absence of claims data, we stated we would use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

For CY 2022, we propose to designate two new CY 2022 CPT codes for ASC covered surgical procedures as temporarily office-based. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures listed in Table 44 would be predominantly performed in physicians' offices. We believe the procedure described by CPT code 42XXX (Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic) is similar to CPT code 31505 (Laryngoscopy, indirect; diagnostic (separate procedure)) which is currently on the list of ASC covered surgical procedures and was assigned a final payment indicator of ''P3''—Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs.—in CY 2021. Additionally, we believe the procedure described by CPT code 53XX4 (Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume) is similar to CPT code 0551T (Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume), which is currently on the list of ASC covered surgical procedures and was assigned a final payment indicator of ''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—for CY 2021. As such, we propose to add CPT codes 42XXX and 53XX4 in Table 44 to the list of ASC covered surgical procedures designated as temporarily office-based for CY 2022.

TABLE 44: PROPOSED CY 2022 PAYMENT INDICATORS FOR NEW CY 2022 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2022 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2022 Long Descriptor	Proposed CY 2022 ASC Payment Indicator**
42XXX	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic	R2**
53XX4	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume	R2**

** Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2022 PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2022 PFS proposed rule.

b. Proposed Device-Intensive ASC Covered Surgical Procedures

(1) Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2022

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 590401 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for CY 2019 and subsequent years, we adopted a policy 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. For consistency with this change in the cost criterion, we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will 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 adopted a policy that the default device offset would be applied in the same

manner as the policy we adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2. of CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, 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 Food and Drug Administration (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 §§ 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:

++ 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

++ 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 these criteria, for 2022, we propose to update the ASC CPL to indicate procedures that are eligible for payment according to our device-intensive procedure payment methodology, based on the proposed individual HCPCS code device-offset percentages using the CY 2019 OPPS claims and cost report data available for the CY 2022 OPPS/ASC proposed rule.

The ASC covered surgical procedures that we propose to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2022, are assigned payment indicator ''J8'' and are included in ASC Addendum AA to this proposed rule (which is available via the internet on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2022 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 are also included in Addendum AA to the proposed rule (which is available via the internet on the CMS website).

Under current policy, the payment rate under the ASC payment system for device-intensive procedures furnished with an implantable or inserted medical device are calculated by applying the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment based on the standard ratesetting methodology 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 (82 FR 59409).

In past rulemaking (79 FR 66924), we have stated that the device-intensive methodology for ASCs should align with the device-intensive policies under the OPPS. Further, we have stated that we do not believe that procedures are device-intensive in one setting and not in another setting. We have heard concerns from stakeholders that our methodology does not provide device-intensive status to certain procedures even though the procedures' device offset percentages are greater than our 30 percent threshold when calculated under the standard ASC ratesetting methodology. We have also heard concerns from stakeholders that procedures designated as device-intensive under the OPPS are not assigned device-intensive status under the ASC payment system even though the procedure has significant device costs.

The different ratesetting methodologies used under the OPPS and ASC payment system can create conflicts when determining device-intensive status. For example, procedures with device offset percentages greater than 30 percent under the OPPS may not have device offset percentages greater than 30 percent when calculated under the standard ASC ratesetting methodology. Under current policy, procedures must be device-intensive in the OPPS setting to be eligible for device-intensive status under the ASC payment system. However, this methodology has caused confusion among stakeholders and has denied device-intensive status to procedures with significant device costs. While we believe that device-intensive policies under the ASC payment system should align with device-intensive policies under the OPPS, we believe device-intensive status under the ASC payment system should, at a minimum, reflect a procedure's estimated device costs under the ASC standard ratesetting methodology. Therefore, for CY 2022 and subsequent years, we are proposing to assign device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS.

Further, in situations where a procedure is designated as device-intensive under the OPPS but the procedure's device offset percentage is below the device-intensive threshold under the standard ASC ratesetting methodology, we believe that deference should be given to the OPPS designation to address this conflict in status. Since the comprehensive ratesetting methodology under the OPPS packages a greater amount of non-device costs into the primary procedure and is typically able to use a greater number of claims in its ratesetting methodology, we believe that if a device receives OPPS device-intensive status, the device should also be device-intensive in the ASC setting, give that fewer non-device costs are generally packaged into a procedure's cost under the ASC methodology compared to the OPPS methodology. Therefore, for CY 2022 and subsequent years, we are proposing that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent.

We are soliciting comments on our proposed changes related to designating surgical procedures as device-intensive under the ASC payment system.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations, and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices.) ASC payment is reduced 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.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a 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 the CY 2014 OPPS/ASC 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.

Under current ASC policy, all ASC device-intensive covered surgical 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 or insert 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 or insert 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.

Effective in CY 2019 (83 FR 59043 through 59044), for partial credit, we adopted a policy 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 will 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 have the option of either: (1) Submitting the claim for the device-intensive 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 or insertion 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 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.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would 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 device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we propose to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and subsequent calendar years. Specifically, for CY 2022 and subsequent calendar years, we would 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 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 device, ASCs have the option of either: (1) Submitting the claim for the device intensive 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 or insertion 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 device. Beneficiary coinsurance would be based on the reduced payment amount. We are not proposing any other changes to our policies related to no/cost full credit or partial credit devices.

d. Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also 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. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made

in response to specific concerns raised by stakeholders.

From CY 2008 through CY 2020, under our regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2008 were surgical procedures that met the general standards specified in § 416.166(b) and were not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 416.166(b), the general standards provided that covered surgical procedures were surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that were separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictated that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Section 416.166(c) set out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provided that covered surgical procedures do not include those surgical procedures that: (1) Generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15. For a discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86143 through 86145).

In the CY 2021 OPPS/ASC Final Rule, we significantly revised our policy for adding surgical procedures to the ASC CPL. We revised the definition of covered surgical procedures at 42 CFR 416.166(a) and (b) to add new subparagraphs to provide that, for services furnished on or after January 1, 2021, covered surgical procedures for purposes of the ASC CPL are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that: Are separately paid under the OPPS; and are not: Designated as requiring inpatient care as of December 31, 2020; only able to be reported using a CPT unlisted surgical procedure code; or otherwise excluded under § 411.15.

We added a new paragraph (d) to 42 CFR 416.166 to provide that the general exclusion and general standard criteria that we used to identify covered surgical procedures furnished between January 1, 2008, and December 31, 2020, would, beginning January 1, 2021, be safety factors that physicians consider as to a specific beneficiary when determining whether to perform a covered surgical procedure. We also added a new paragraph (e) to 42 CFR 416.166 to provide that, on or after January 1, 2021, we add surgical procedures to the list of ASC covered surgical procedures either when we identify a surgical procedure that meets the requirements of paragraph (b)(2) or we are notified of a surgical procedure that could meet the requirements of paragraph (b)(2) and we confirm that such procedure meets those requirements. We added 267 surgical procedures to the ASC CPL that met the revised criteria for covered surgical procedures beginning in CY 2021.

As we explained in the CY 2021 OPPS/ASC final rule with comment period, there were a number of reasons that we made changes to our ASC CPL policy, including that ASCs are increasingly able to safely provide services that meet some of the general exclusion criteria. We explained that we believed it was important that we adapt the ASC CPL in light of significant advances in medical practice, surgical techniques, and ASC capabilities (85 FR 86150). We stated that, while many of the procedures we were adding to the ASC CPL were performed on non-Medicare patients who tend to be younger and have fewer comorbidities than the Medicare population, we believed careful patient selection can identify Medicare beneficiaries who are suitable candidates to receive these services in the ASC setting. We also emphasized the importance of ensuring that the healthcare system has as many access points and patient choices for Medicare beneficiaries as possible, which includes enabling physicians and patients to choose the ASC as the site of care when appropriate. Finally, we reiterated the critical role that physicians play in determining the appropriate site of care for their patients, including whether a surgical procedure can be safely performed in the ASC setting for an individual patient.

1. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2022

Since the CY 2021 OPPS/ASC final rule was published, we have reexamined our ASC CPL policy and the public comments we received in response to the CY 2021 OPPS/ASC proposed rule, considered the concerns we received from stakeholders since the final rule was published, and conducted an internal clinical review of the 267 procedures we added to the ASC CPL under our revised policy beginning in CY 2021. After examining our revised policy and the feedback we have received, and reviewing the procedures we added to the ASC CPL under our revised policy, we have reconsidered our policy and believe that the policy may not appropriately assess the safety of performing surgical procedures on a typical Medicare beneficiary in an ASC, and that the 258 surgical procedures we added to the ASC CPL beginning in CY 2021 under our revised policy may not be appropriate to be performed on a typical beneficiary in the ASC setting. We believe that our current policy—to shift consideration of the general standards and exclusion criteria we have historically used to determine whether a surgical procedure should be added to the ASC CPL from CMS to physicians—needs to be modified to better ensure that surgical procedures added to the ASC CPL under the revised criteria can be performed safely in the ASC setting on the typical Medicare beneficiary. We recognize that appropriate patient selection and physicians' complex medical judgment could help mitigate risks for patient safety. But while we are always striving to balance the goals of increasing physician and patient choice, and expanding site neutral options with patient safety considerations, we nonetheless believe the current policy could be improved with additional patient safety considerations in determining whether a surgical procedure should be added to the ASC CPL.

One issue we identified with our revised policy is that many of the procedures added in CY 2021 would only be appropriate for Medicare beneficiaries who are healthier and have less complex medical conditions than the typical beneficiary. Upon further review, we believe the subset of Medicare beneficiaries who may be suitable candidates to receive these procedures in an ASC setting do not necessarily represent the average Medicare beneficiary. After evaluating the 267 surgery or surgery-like codes

that were added last year, CMS clinicians determined that 258 of these surgical procedures may pose a significant safety risk to a typical Medicare beneficiary when performed in an ASC, and that nearly all would likely require active medical monitoring and care at midnight following the procedure. In the CY 2021 OPPS/ASC Final Rule, we established that physicians would consider certain safety factors as to a specific beneficiary when determining whether to perform a covered surgical procedure in an ASC. However, while a physician can make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries.

While there could be some appropriately selected patient populations for which some of these procedures could be safely performed in the ASC setting, that may not be the case for the typical Medicare beneficiary, due to comorbidities and other health risks that may require more intensive care and monitoring than provided in an ASC setting among this population. We believe it is appropriate to assess the safety of these procedures in the context of the typical Medicare beneficiary, whose health status is representative of the broader Medicare population. Thus, we believe evaluating procedures for their potential to require additional care and monitoring for the typical beneficiary is an appropriate consideration for CMS to make in determining which procedures can safely be performed in an ASC.

We are concerned that, under our current policy, we do not make an active enough determination about whether a procedure is suitable to perform on a typical Medicare beneficiary in an ASC setting. The policy finalized last year allows individual physicians discretion to perform a number of procedures in the ASC setting that would not necessarily be appropriate for the typical Medicare beneficiary in that setting. Clinicians apply appropriate screening criteria to determine either that the procedure should not be performed in the ASC setting because of the risks to the specific beneficiary, or that the specific beneficiary presents a low enough risk profile that the procedure could be safely performed in the ASC setting.

However, we want to reiterate that, in accordance with section 1833(i)(1)(A) of the Act, the Secretary shall specify those surgical procedures that are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but that also can be performed safely on an ambulatory basis in an ambulatory surgical center. That is, if Medicare allows payment for these services in the ASC setting, it means that Medicare has determined that the procedure is safe to perform on the typical Medicare beneficiary.

Accordingly, the addition of a procedure to the ASC CPL can signal to physicians that the procedure is safe to perform on the typical Medicare beneficiary in the ASC setting, even though the current criteria, adopted in CY 2021, for adding procedures to the ASC CPL do not include safety criteria other than ensuring that the procedure was not on the IPO list as of CY 2020. We recognize that, while there are similarities between the ASC and HOPD settings, there are also significant differences between the two care settings. The HOPD setting has additional capabilities, resources, and certifications that are not required for the ASC setting. For example, hospitals operate 24/7 and are subject to EMTALA requirements, while ASCs are not. Therefore, a procedure that can be furnished in the HOPD setting is not necessarily safe and appropriate to perform in an ASC setting simply because we make payment for the procedure when it is furnished in the HOPD setting.

In light of these concerns, in this CY 2022 OPPS/ASC proposed rule, we propose to revise the criteria and process for adding procedures to the ASC CPL by reinstating the ASC CPL policy and regulation text that were in place in CY 2020. While this approach is a departure from the revised policy we adopted for CY 2021, it is consistent with our policy from CY 2008 through CY 2020 where we gradually expanded the ASC CPL while giving careful consideration to safety concerns and risks to the typical beneficiary. This approach would also continue to support our efforts to maximize patient access to care by, when appropriate, adding procedures to the ASC CPL to further increase the availability of ASCs as an alternative, lower cost site of care. While expanding the ASC CPL offers benefits like preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, it is also essential that any expansion of the ASC CPL be done in a carefully calibrated fashion to ensure that Medicare is appropriately signaling that a procedure is safe to be performed in the ASC setting for a typical Medicare beneficiary.

Accordingly, for CY 2022, we propose to revise the requirements for covered surgical procedures in the regulation at § 416.166 to reinstate the specifications we had established prior to CY 2021. Specifically, we propose that, effective for services furnished on or after January 1, 2022, covered surgical procedures are those procedures that meet the general standards and do not meet the general exclusions. We propose to again provide in paragraph (b) of § 416.166 that, subject to the exclusions we propose to again include in paragraph (c), covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary 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. We propose to revise paragraph (c) to again include the five criteria currently included in paragraph (d) of the regulation as safety factors physicians consider. We propose that revised paragraph (c) would provide that, notwithstanding paragraph (b), covered surgical procedures do not include those surgical procedures that: (1) Generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15. We propose to remove the physician considerations at § 416.166(d) and change the notification process at § 416.166(e) to a nomination process, which is discussed further in section (d)(2) below.

We expect that we would continue to expand the ASC CPL in future years under our proposed revised criteria as the practice of medicine and medical technology continue to evolve. We believe that adding appropriate procedures to the ASC CPL, that meet the safety criteria that we are proposing to reinstate, has beneficial effects for Medicare beneficiaries and healthcare professionals, including increased access, better utilization of existing healthcare resources, and expansion of the capacity of the healthcare system.

(1) Comment Solicitation on Procedures That Were Added to the ASC CPL in CY 2021 and Would Not Meet the Proposed Revised CY 2022 Criteria

As stated above, we are proposing to remove 258 procedures from the ASC CPL for CY 2022 that were added to the ASC CPL in CY 2021 that we believe do not meet the proposed revised CY 2022 ASC CPL criteria, listed in Table 45. Based on our internal review of preliminary claims submitted to Medicare, we do not believe that ASCs have been furnishing the majority of the 267 procedures finalized in 2021. Because of this, we believe it is unlikely that ASCs have made practice changes in reliance on the policy we adopted in CY 2021. Therefore, we do not anticipate that ASCs would be significantly affected by the removal of these 258 procedures from the ASC CPL. For the final rule, we seek input from commenters who believe any of the 258 procedures added to the ASC CPL in CY 2021 meet the proposed revised CY 2022 criteria and, if those revised criteria are finalized, should remain on the ASC CPL for CY 2022. We request any clinical evidence or literature to support commenters' views that any of these procedures meet the proposed revised CY 2022 criteria and should remain on the ASC CPL for CY 2022.

Nomination Process Proposal

For CY 2022, we propose to change the current notification process for adding surgical procedures to the ASC CPL to a nomination process. We propose that external parties, for example, medical specialty societies or other members of the public, could nominate procedures to be added to the ASC CPL. CMS anticipates that stakeholders, such as specialty societies that specialize in and have a deep understanding of the complexities involved in providing certain procedures, would be able to provide valuable suggestions as to which additional procedures may reasonably and safely be performed in an ASC. While members of the public may already suggest procedures to be added to the ASC CPL through meetings with CMS or through public comments on the proposed rule, we believe it may be beneficial to enable the public, particularly specialty societies who are very familiar with procedures in their specialty, to formally nominate procedures based on the latest evidence available as well as input from their memberships.

We propose to include the nomination process in a new subparagraph (d)(1) of § 416.166. We propose that the regulation at § 416.166(d)(2) would provide that, if we identify a surgical procedure that meets the requirements at paragraph (a) of this section, including a surgical procedure nominated by an external party under paragraph (d)(1), we will propose to add the surgical procedure to the list of ASC covered surgical procedures in the next available annual rulemaking. Under this proposal, we would propose to add a nominated procedure to the ASC CPL if it meets the proposed general standards for covered surgical procedures at proposed § 416.166(b), and does not meet the general exclusions in proposed § 416.166(c).

Specifically, for the OPPS/ASC rulemaking for a calendar year, we would request stakeholder nominations by March 1 of the year prior to the calendar year for the next applicable rulemaking cycle in order to be included in that rulemaking cycle. For example, stakeholders would need to send in nominations by March 1, 2022, to be considered for the CY 2023 rulemaking cycle and potentially have their nomination effective by January 1, 2023. We would evaluate procedures nominated by stakeholders based on the applicable statutory and regulatory requirements for ASC covered surgical procedures. We propose to address nominated procedures beginning in the CY 2023 rulemaking cycle. We would address in rulemaking nominated procedures for which stakeholders have provided sufficient information for us to evaluate the procedure. We propose to include in the applicable proposed rule, a summary of the justification for proposing to add or not add each nominated procedure, which would allow members of the public to assess and comment on nominated procedures during the public comment period. After reviewing comments provided during the public comment period, we would indicate whether or not we are adding the procedures to ASC CPL in the final rule. In the event that CMS determines that a nominated procedure does not meet the criteria to be added to the ASC CPL, we would provide our rationale in the rulemaking. In certain cases, we may need to defer a proposal regarding a nominated procedure to the next regulatory cycle or future rulemaking in order to have sufficient time to evaluate and make an appropriate proposal about the nominated procedure.

We are also seeking comment on how we might prioritize our review of nominated procedures, in the event we receive an unexpectedly or extraordinarily large volume of nominations for which CMS has insufficient resources to address in the annual rulemaking. For example, if we could not address every nomination in a rulemaking cycle due to a large volume, we may need to prioritize our review such that we would only address in rulemaking those nominations that merit priority. Therefore, we are seeking comments as to how CMS should prioritize nominations. For example, whether we would prioritize the nominations that have codes nominated by multiple organizations or individuals, codes recently removed from the IPO list, codes accompanied by evidence that other payers are paying for the service on an outpatient basis or in an ASC setting, or a variety of other factors. If we were to finalize a prioritization hierarchy for CMS's review of nominated procedures to the ASC CPL, we would indicate in regulation text, likely in proposed § 416.166(d)(2) *Inclusion in Rulemaking:* (1) That CMS would apply a prioritization hierarchy for reviewing nominated procedures if necessary because of an unexpectedly or extraordinarily large volume of nominations; and (2) specify CMS's prioritization hierarchy.

We believe that this nominations proposal allows for the expansion of the ASC CPL in a more gradual fashion, which would better balance the goals of increasing patient choice and expanding site neutral options with patient safety considerations. We believe a nomination process will take time to develop because we want to incorporate stakeholder input on the most effective way to structure this process. We also acknowledge that stakeholders will need time to consider and evaluate potential surgical procedures to nominate. We propose to accept nominations for surgical procedures to be added to the ASC CPL beginning in CY 2023.

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TABLE 45: SURGICAL PROCEDURES PROPOSED FOR REMOVAL FROM THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2022

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	G2
20100	Exploration of penetrating wound (separate procedure); neck	G2
20101	Exploration of penetrating wound (separate procedure); chest	G2
20102	Exploration of penetrating wound (separate procedure); abdomen/flank/back	G2
20660	Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)	G2
21049	Excision of benign tumor or cyst of maxilla; requiring extra-oral osteotomy and partial maxillectomy (eg, locally aggressive or destructive lesion[s])	G2
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)	G2
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (eg, plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)	G2
21193	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; without bone graft	G2
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	J8

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
21256	Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (eg, micro-ophthalmia)	G2
21261	Periorbital osteotomies for orbital hypertelorism, with bone grafts; combined intra- and extracranial approach	G2
21263	Periorbital osteotomies for orbital hypertelorism, with bone grafts; with forehead advancement	G2
21346	Open treatment of nasomaxillary complex fracture (lefort ii type); with wiring and/or local fixation	G2
21385	Open treatment of orbital floor blowout fracture; transantral approach (caldwell-luc type operation)	G2
21386	Open treatment of orbital floor blowout fracture; periorbital approach	G2
21387	Open treatment of orbital floor blowout fracture; combined approach	G2
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)	G2
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)	G2
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints	J8
21601	Excision of chest wall tumor including rib(s)	G2
21742	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), without thoracoscopy	G2
21743	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), with thoracoscopy	G2
22100	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical	G2
22101	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic	G2
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	J8
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	J8
24150	Radical resection of tumor, shaft or distal humerus	G2
24935	Stump elongation, upper extremity	G2
25170	Radical resection of tumor, radius or ulna	G2
25909	Amputation, forearm, through radius and ulna; re-amputation	G2
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
27027	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle), unilateral	G2
27057	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle) with debridement of nonviable muscle, unilateral	G2
27179	Open treatment of slipped femoral epiphysis; osteoplasty of femoral neck (heyman type procedure)	G2
27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	G2
27477	Arrest, epiphyseal, any method (eg, epiphysiodesis); tibia and fibula, proximal	J8
27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (eg, genu varus or valgus)	G2
27722	Repair of nonunion or malunion, tibia; with sliding graft	J8
28360	Reconstruction, cleft foot	G2
28805	Amputation, foot; transmetatarsal	G2
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral	G2
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	G2
31292	Nasal/sinus endoscopy, surgical, with orbital decompression; medial or inferior wall	G2
31293	Nasal/sinus endoscopy, surgical, with orbital decompression; medial and inferior wall	G2
31294	Nasal/sinus endoscopy, surgical, with optic nerve decompression	G2
31584	Laryngoplasty; with open reduction and fixation of (eg, plating) fracture, includes tracheostomy, if performed	G2
31587	Laryngoplasty, cricoid split, without graft placement	G2
31600	Tracheostomy, planned (separate procedure);	G2
31601	Tracheostomy, planned (separate procedure); younger than 2 years	G2
31610	Tracheostomy, fenestration procedure with skin flaps	G2
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J8
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J8
31785	Excision of tracheal tumor or carcinoma; cervical	G2
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	G2
32560	Instillation, via chest tube/catheter, agent for pleurodesis (eg, talc for recurrent or persistent pneumothorax)	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
32561	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); initial day	G2
32562	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day	G2
32601	Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without biopsy	G2
32604	Thoracoscopy, diagnostic (separate procedure); pericardial sac, with biopsy	G2
32606	Thoracoscopy, diagnostic (separate procedure); mediastinal space, with biopsy	G2
32607	Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral	G2
32608	Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral	G2
32609	Thoracoscopy; with biopsy(ies) of pleura	G2
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	G2
33272	Removal of subcutaneous implantable defibrillator electrode	G2
34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision	G2
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision	G2
34201	Embolectomy or thrombectomy, with or without catheter; femoropopliteal, aortoiliac artery, by leg incision	G2
34203	Embolectomy or thrombectomy, with or without catheter; popliteal-tibio-peroneal artery, by leg incision	G2
34421	Thrombectomy, direct or with catheter; vena cava, iliac, femoropopliteal vein, by leg incision	G2
34471	Thrombectomy, direct or with catheter; subclavian vein, by neck incision	G2
34501	Valvuloplasty, femoral vein	G2
34510	Venous valve transposition, any vein donor	G2
34520	Cross-over vein graft to venous system	G2
34530	Saphenopopliteal vein anastomosis	G2
35011	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm and associated occlusive disease, axillary-brachial artery, by arm incision	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery	G2
35180	Repair, congenital arteriovenous fistula; head and neck	G2
35184	Repair, congenital arteriovenous fistula; extremities	G2
35190	Repair, acquired or traumatic arteriovenous fistula; extremities	G2
35201	Repair blood vessel, direct; neck	G2
35206	Repair blood vessel, direct; upper extremity	G2
35226	Repair blood vessel, direct; lower extremity	G2
35231	Repair blood vessel with vein graft; neck	G2
35236	Repair blood vessel with vein graft; upper extremity	G2
35256	Repair blood vessel with vein graft; lower extremity	G2
35261	Repair blood vessel with graft other than vein; neck	G2
35266	Repair blood vessel with graft other than vein; upper extremity	G2
35286	Repair blood vessel with graft other than vein; lower extremity	G2
35321	Thromboendarterectomy, including patch graft, if performed; axillary-brachial	G2
35860	Exploration for postoperative hemorrhage, thrombosis or infection; extremity	G2
35879	Revision, lower extremity arterial bypass, without thrombectomy, open; with vein patch angioplasty	G2
35881	Revision, lower extremity arterial bypass, without thrombectomy, open; with segmental vein interposition	G2
35883	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with nonautogenous patch graft (eg, dacron, eptfe, bovine pericardium)	G2
35884	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with autogenous vein patch graft	G2
35903	Excision of infected graft; extremity	G2
36460	Transfusion, intrauterine, fetal	G2
36838	Distal revascularization and interval ligation (dril), upper extremity hemodialysis access (steal syndrome)	G2
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recannulization/dilatation, stent placement and all associated imaging guidance and documentation)	J8

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J8
37192	Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J8
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	G2
37195	Thrombolysis, cerebral, by intravenous infusion	G2
37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;	G2
37214	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed; cessation of thrombolysis including removal of catheter and vessel closure by any method	G2
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	J8
37565	Ligation, internal jugular vein	G2
37600	Ligation; external carotid artery	G2
37605	Ligation; internal or common carotid artery	G2
37606	Ligation; internal or common carotid artery, with gradual occlusion, as with selverstone or crutchfield clamp	G2
37615	Ligation, major artery (eg, post-traumatic, rupture); neck	G2
37619	Ligation of inferior vena cava	G2
38120	Laparoscopy, surgical, splenectomy	G2
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor	G2
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor	G2
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, t-cell depletion	G2
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion	G2
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal	G2
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion	G2
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion	G2
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer	G2
38240	Hematopoietic progenitor cell (hpc); allogeneic transplantation per donor	G2
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	G2
38720	Cervical lymphadenectomy (complete)	G2
39401	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (eg, lymphoma), when performed	G2
39402	Mediastinoscopy; with lymph node biopsy(ies) (eg, lung cancer staging)	G2
42842	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; without closure	G2
42844	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (eg, tongue, buccal)	G2
43020	Esophagotomy, cervical approach, with removal of foreign body	G2
43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, nissen, toupet procedures)	G2
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	G2
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	G2
43420	Closure of esophagostomy or fistula; cervical approach	G2
43510	Gastrotomy; with esophageal dilation and insertion of permanent intraluminal tube (eg, celestin or mousseaux-barbin)	G2
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum	J8
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum	G2
43651	Laparoscopy, surgical; transection of vagus nerves, truncal	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
43652	Laparoscopy, surgical; transection of vagus nerves, selective or highly selective	G2
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	J8
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	G2
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	G2
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	G2
43830	Gastrostomy, open; without construction of gastric tube (eg, stamm procedure) (separate procedure)	G2
43831	Gastrostomy, open; neonatal, for feeding	G2
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	G2
44186	Laparoscopy, surgical; jejunostomy (eg, for decompression or feeding)	G2
44950	Appendectomy;	G2
44955	Appendectomy; when done for indicated purpose at time of other major procedure (not as separate procedure) (list separately in addition to code for primary procedure)	N1
44970	Laparoscopy, surgical, appendectomy	G2
47370	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency	G2
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical	G2
47490	Cholecystostomy, percutaneous, complete procedure, including imaging guidance, catheter placement, cholecystogram when performed, and radiological supervision and interpretation	G2
49185	Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (eg, ultrasound, fluoroscopy) and radiological supervision and interpretation when performed	G2
49323	Laparoscopy, surgical; with drainage of lymphocele to peritoneal cavity	G2
49405	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
49491	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; reducible	G2
49492	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; incarcerated or strangulated	G2
50020	Drainage of perirenal or renal abscess, open	G2
50541	Laparoscopy, surgical; ablation of renal cysts	G2
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	G2
50543	Laparoscopy, surgical; partial nephrectomy	G2
50544	Laparoscopy, surgical; pyeloplasty	G2
50945	Laparoscopy, surgical; ureterolithotomy	G2
51060	Transvesical ureterolithotomy	G2
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, stamey, raz, modified pereyra)	G2
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple	G2
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	G2
53500	Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (eg, postsurgical obstruction, scarring)	G2
54332	1-stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54336	1-stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54535	Orchiectomy, radical, for tumor; with abdominal exploration	G2
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, fowler-stephens)	G2
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
55970	Intersex surgery; male to female	G2
55980	Intersex surgery; female to male	G2
57106	Vaginectomy, partial removal of vaginal wall;	G2
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)	G2
57109	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)	G2
57284	Paravaginal defect repair (including repair of cystocele, if performed); open abdominal approach	G2
57285	Paravaginal defect repair (including repair of cystocele, if performed); vaginal approach	G2
57292	Construction of artificial vagina; with graft	G2
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach	G2
57335	Vaginoplasty for intersex state	G2
57423	Paravaginal defect repair (including repair of cystocele, if performed), laparoscopic approach	G2
57555	Excision of cervical stump, vaginal approach; with anterior and/or posterior repair	G2
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele	G2
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele	G2
58290	Vaginal hysterectomy, for uterus greater than 250 g;	G2
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele	G2
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele	G2
58770	Salpingostomy (salpingoneostomy)	G2
58920	Wedge resection or bisection of ovary, unilateral or bilateral	G2
58925	Ovarian cystectomy, unilateral or bilateral	G2
59030	Fetal scalp blood sampling	G2
59409	Vaginal delivery only (with or without episiotomy and/or forceps);	G2
59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	G2
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid	G2
60271	Thyroidectomy, including substernal thyroid; cervical approach	G2
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	G2
60512	Parathyroid autotransplantation (list separately in addition to code for primary procedure)	N1
60520	Thymectomy, partial or total; transcervical approach (separate procedure)	G2
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injury post occlusion	J8
61626	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)	J8
61720	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus	G2
62000	Elevation of depressed skull fracture; simple, extradural	G2
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy	G2
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; sacral	G2
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (gill type procedure)	G2
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; cervical	G2
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; thoracic	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; lumbar	G2
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (list separately in addition to code for primary procedure)	N1
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical	G2
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (list separately in addition to code for primary procedure)	N1
63048	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; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	N1
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (list separately in addition to code for primary procedure)	N1
63064	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; single segment	G2
63066	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; each additional segment (list separately in addition to code for primary procedure)	N1
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace	G2
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (list separately in addition to code for primary procedure)	N1
63741	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; percutaneous, not requiring laminectomy	J8
64804	Sympathectomy, cervicothoracic	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
64911	Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve	G2
69725	Decompression facial nerve, intratemporal; including medial to geniculate ganglion	G2
69955	Total facial nerve decompression and/or repair (may include graft)	G2
69960	Decompression internal auditory canal	G2
69970	Removal of tumor, temporal bone	G2
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J8
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)	N1
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	J8
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)	N1
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	J8
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	N1
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]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	G2

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
C9758	Blinded procedure for nyha class iii/iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	G2
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, tems), including muscularis propria (ie, full thickness)	G2
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar	G2
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	G2
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (egj), with implantation of pulse generator, includes programming	G2
0453T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; mechano-electrical skin interface	G2
0454T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; subcutaneous electrode	G2
0457T	Removal of permanently implantable aortic counterpulsation ventricular assist system; mechano-electrical skin interface	G2
0458T	Removal of permanently implantable aortic counterpulsation ventricular assist system; subcutaneous electrode	G2
0460T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode	G2
0499T	Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed	G2
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	J8

CY 2022 CPT/ HCPCS Code	CY 2022 Long Descriptor	Final CY 2021 ASC Payment Indicator
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])	J8
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	G2
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) (battery and/or transmitter) only	J8
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing	G2
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	J8
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	J8

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2. Covered Ancillary Services

We are proposing to continue our existing policies relating to covered ancillary services with a proposed revision to the regulation at 42 CFR 416.164(b)(6) regarding our policy related to payment for non-opioid pain management drugs and biologicals.

In the CY 2019 OPPS/ASC final rule (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2019 OPPS final rule. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services because of changes that are being finalized under the OPPS for CY 2022. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2021, but will be packaged under the CY 2022 OPPS, to maintain consistency with the OPPS, we would also package the ancillary service under the ASC payment system for CY 2022. In the CY 2019 OPPS/ASC final rule, we finalized the policy to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH'', which is discussed in section XIII.F. of the CY 2021 OPPS/ASC proposed rule, is used in Addendum BB to this CY 2022 OPPS/ASC final rule (which is available via the internet on the CMS website) to indicate covered ancillary services for which we are finalizing a change in the ASC payment indicator to reflect a finalized change in the OPPS treatment of the service for CY 2021.

For CY 2022, as discussed in section II.A.3.b, we propose to revise 42 CFR 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS in proposed new § 416.174.

New CPT and HCPCS codes for covered ancillary services and their proposed payment indicators for CY 2022 can be found in section XIII.B of this CY 2022 OPPS/ASC proposed rule. All ASC covered ancillary services and their proposed payment indicators for CY 2022 are also included in Addendum BB to this CY 2022 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

D. Proposed Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are 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 only the service portion of the rate is subject to the ASC conversion factor. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86122 through 86179), we updated the CY 2020 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2019 data, consistent with the CY 2021 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2021 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 or the amount calculated using the ASC standard rate setting methodology for the procedure. In the CY 2021 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 2021 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 2021 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 procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (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 ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator ''Q2'')—we continued to provide separate payment since CY 2014 and assigned the current ASC payment indicators associated with these procedures.

b. Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. The reduced coinsurance will be phased-in beginning January 1, 2022. Our proposals to implement this legislation are included in the CY 2022 PFS proposed rule and section X.B., ''Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests'' of this proposed rule.

c. Proposed Update to ASC Covered Surgical Procedure Payment Rates for CY 2022

We propose to update ASC payment rates for CY 2022 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 this CY 2022 OPPS/ASC proposed rule. Because the proposed OPPS relative payment weights are generally based on geometric mean costs, the ASC system would generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We propose 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 this CY 2022 OPPS/ASC proposed rule. Therefore, we propose to update the payment amount for the service portion of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2022 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 2022 MPFS nonfacility PE RVU-based amount or the proposed CY 2022 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2021, for CY 2022 we propose 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 those procedures and would continue to be paid separately under the ASC payment system.

d. Proposed Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b. of this CY 2022 OPPS/ASC proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology. However, for low-volume device-intensive procedures, the proposed relative payment weights are based on median costs, rather than geometric mean costs, as discussed in section IV.B.5. of this CY 2022 OPPS/ASC proposed rule.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61400), we finalized our policy to limit the ASC payment rate for low-volume device-intensive procedures to a payment rate equal to the OPPS payment rate for that

procedure. Under this policy, where the ASC payment rate based on the standard ASC ratesetting methodology for low volume device-intensive procedures would exceed the rate paid under the OPPS for the same procedure, we establish an ASC payment rate for such procedures equal to the OPPS payment rate for the same procedure.

As discussed in Section X of this CY 2022 OPPS/ASC proposed rule, we are proposing a low volume APC policy for CY 2022 and subsequent calendar years. Under our proposal, a clinical APC, brachytherapy APC, or new technology APC with fewer than 100 claims per year would be designated as a low volume APC. For items and services assigned to APCs we propose to designate as low volume APCs, we are proposing to use up to 4 years of claims data to establish a payment rate for each item or service as we currently do for low volume services assigned to New Technology APCs. The payment rate for a low volume APC would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data. Because we are proposing to adopt a low volume APC policy, we are also proposing to eliminate our low volume device-intensive procedure policy and subsume the ratesetting issues associated with HCPCS code 0308T within our broader low volume APC proposal. Consequently, we are proposing to modify our existing regulations at § 416.171(b)(4) to apply our ASC payment rate limitation to services assigned to low volume APCs rather than low volume device-intensive procedures.

We seek comments on our proposal to modify our existing regulations at § 416.171(b)(4) and limit the ASC payment rate for services assigned to low volume APCs to the payment rate for the OPPS.

2. Proposed Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally 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 for procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged procedure 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 procedures, as discussed in section IV. of this CY 2022 OPPS/ASC 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 and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in section XIII.D.3. of this CY 2022 OPPS/ASC proposed rule, for CY 2022, we are proposing a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under proposed new § 416.174. 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 (§ 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 (§ 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; § 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. Proposed Payment for Covered Ancillary Services for CY 2022

We propose 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 2022 OPPS and ASC payment rates and subsequent year payment rates. We also propose to continue to set the CY 2022 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 2022 and subsequent year payment rates.

Covered ancillary services and their proposed payment indicators for CY 2022 are listed in Addendum BB of this CY 2022 OPPS/ASC 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 final 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, 2022. For a discussion of the PFS rates, we refer readers to the CY 2022 PFS proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

3. CY 2022 ASC Packaging Policy for Non-Opioid Pain Management Drugs and Biologicals

Please refer to Section II.A.3.b for a discussion of the proposed CY 2022 OPPS/ASC for payment for non-opioid pain management drugs and biologicals.

E. Proposed 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 § 416.195.

1. NTIOL Application Cycle

Our 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 requested 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 § 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 2022

We did not receive any requests for review to establish a new NTIOL class for CY 2022 by March 1, 2021, the due date published in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86173).

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 2022.

F. Proposed 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 included 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 ''NI'' is used in the OPPS/ASC final rule to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed 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, and the proposed payment indicator assigned is subject to comment, as discussed in 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 2021 OPPS/ASC final rule, we finalized the addition of ASC payment indicator ''K5''—Items, Codes, and Services for which pricing information and claims data are not available. No payment made.—to ASC Addendum DD1 (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

2. ASC Payment and Comment Indicators for CY 2022

For 2022, we propose 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 2022 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2022, compared to the CY 2021 descriptors, are included in ASC Addenda AA and BB to this proposed rule and labeled with proposed comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of this proposed rule. Proposed comment indicator ''NP'' meant 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 the current calendar year; and denoted that comments would be accepted on the proposed ASC payment indicator for the new code.

We will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2022 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 of this 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 2022 update. Addenda DD1 and DD2 to this proposed rule (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2022.

G. Proposed 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; § 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 CY

2022 OPPS/ASC proposed rule), 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.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. 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.

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. 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. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf*).

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. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*).

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wpcontent/uploads/2018/90/Bulletin-18-04.pdf*. We are utilizing the revised delineations as set forth in the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 to calculate the CY 2021 ASC wage index effective beginning January 1, 2021.

For CY 2022, we noted that the proposed CY 2022 ASC wage indexes fully reflects 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, 17–01, 18–03, and 18–04). 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 2022, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

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 have continued 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 2022 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). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system equal to what would be the current expenditures based on the scaled ASC payment weights. In this way we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC

expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would increase at a lower rate than payment for the same procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

As discussed in Section II.A.1.a of this proposed rule, given our concerns with CY 2020 claims data as a result of the PHE, we are using the CY 2019 claims data to be consistent with the OPPS claims data for this CY 2022 OPPS/ASC proposed rule. Consistent with our established policy, we propose to scale the CY 2022 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 2019, we propose to compare the total payment using the CY 2021 ASC relative payment weights with the total payment using the CY 2022 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2021 and CY 2022. We propose to use the ratio of CY 2021 to CY 2022 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2022. The proposed CY 2022 ASC weight scalar is 0.8591. Consistent with historical practice, we would scale the ASC relative payment weights of 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 this proposed rule, we have available 100 percent of CY 2019 ASC claims data.

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 2022, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2019 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2022 ASC wage indexes. Specifically, holding CY 2019 ASC utilization, service-mix, and the proposed CY 2022 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2021 ASC wage indexes and the total adjusted payment using the proposed CY 2022 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 2021 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2022 ASC wage indexes and applied the resulting ratio of 0.9999 (the proposed CY 2022 ASC wage index budget neutrality adjustment) to the CY 2021 ASC conversion factor to calculate the proposed CY 2022 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 § 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 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized our proposal to apply the productivity-adjusted 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 productivity-adjusted 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 finalized our proposal to revise our regulations under § 416.171(a)(2), which address the annual update to the ASC conversion factor. 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. We refer readers to that final rule for a detailed discussion of the rationale for these policies.

The proposed hospital market basket update for CY 2022 is projected to be 2.5 percent, as published in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435), based on IHS Global Inc.'s (IGI's) 2020 fourth quarter forecast with historical data through the third quarter of 2020.

Section 1886(b)(3)(B)(xi)(II) of the 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). We finalized the methodology for calculating the productivity 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). The proposed productivity adjustment for CY 2022 is projected to be 0.2 percentage point, as published in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25435) based on IGI's 2020 fourth quarter forecast.

For 2022, we propose to utilize the hospital market basket update of 2.5 percent reduced by the productivity adjustment of 0.2 percentage point, resulting in a productivity-adjusted hospital market basket update factor of 2.3 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a 2.3 percent productivity-adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2022 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 refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E. of this CY 2022 OPPS/ASC proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We propose to utilize the hospital market basket update of 2.5 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the 0.2 percentage point productivity adjustment. Therefore, we propose to apply a 0.3 percent productivity-adjusted hospital market basket update factor to the CY 2021 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also propose that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update or productivity adjustment), we would use such data, if appropriate, to determine the CY 2022 ASC update for the CY 2022 OPPS/ASC final rule with comment period.

For 2022, we propose to adjust the CY 2021 ASC conversion factor ($48.952) by the proposed wage index budget neutrality factor of 0.9993 in addition to the productivity-adjusted hospital market basket update of 2.3 percent discussed above, which results in a proposed CY 2022 ASC conversion factor of $50.043 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we propose to adjust the CY 2021 ASC conversion factor ($48.952) by the proposed wage index budget neutrality factor of 0.9993 in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.3 percent discussed above, which results in a proposed CY 2022 ASC conversion factor of $49.064.

3. Display of Proposed CY 2022 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2022 for covered surgical procedures and covered ancillary services, respectively. Historically, for those covered surgical procedures and covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard ratesetting methodology and the MPFS proposed rates, the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the PFS rates that would be effective January 1, 2022. For a discussion of the PFS rates, we refer readers to the CY 2022 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*.

The proposed payment rates included in addenda AA and BB to this proposed rule 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 proposed CY 2022 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 2021. 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.

For 2021, we finalized adding a new column to ASC Addendum BB titled ''Drug Pass-Through Expiration during Calendar Year'' where we flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

The values displayed in the column titled ''Proposed CY 2021 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2021. The proposed 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. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2022 payment rate displayed in the ''Proposed CY 2022 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2022 Payment Weight'' column was multiplied by the proposed CY 2022 conversion factor of $50.043. The 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. The proposed CY 2022 ASC conversion factor uses the CY 2022 productivity-adjusted hospital market basket update factor of 2.3 percent (which is equal to the projected hospital market basket update of 2.5 percent reduced by a projected productivity adjustment of 0.2 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2022 Payment Weight'' column for items and services

with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2021 Payment'' column displays the proposed CY 2022 national unadjusted ASC payment rates for all items and services. The proposed CY 2022 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 2020.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2022.

XIV. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Outpatient Quality Programs—Request for Information

We aim to move fully to digital quality measurement in the Centers for Medicare & Medicaid Services (CMS) quality reporting and value-based purchasing (VBP) programs by 2025. As part of this modernization of our quality measurement enterprise, we are issuing this request for information (RFI). The purpose of this RFI is to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary. This RFI contains five parts:

- Background. This part provides information on our quality measurement programs and our goal to move fully to digital quality measurement by 2025. This part also provides a summary of recent HHS policy developments that are advancing interoperability and could support our move towards full digital quality measurement.
- Definition of Digital Quality Measures (dQMs). This part provides a potential definition for dQMs. Specific requests for input are included in the section.
- Use of Fast Healthcare Interoperability Resources (FHIR®) for Current Electronic Clinical Quality Measures (eCQMs). This part provides information on current activities underway to align CMS eCQMs with the FHIR standard and support quality measurement via application programming interfaces (APIs), and contrasts this approach to current eCQM standards and practice.
- Changes Under Consideration to Advance Digital Quality Measurement: Potential Actions in Four Areas to Transition to dQMs by 2025. This part introduces four possible steps that would enable transformation of CMS' quality measurement enterprise to be fully digital by 2025. Specific requests for input are included in the section.
- Solicitation of Comments. This part lists all requests for input included in the sections of this RFI.

A. Background

As required by law, we implement quality measurement and VBP programs across a broad range of inpatient acute care, outpatient, and post-acute care (PAC) settings consistent with our mission to improve the quality of health care for Americans through measurement, transparency, and increasingly, value-based purchasing. These quality programs are foundational for incentivizing value-based care, contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. In October 2017, we launched the Meaningful Measures Framework. This framework for quality measurement captures our vision to better address health care quality priorities and gaps, including emphasizing digital quality measurement, reducing measurement burden, and promoting patient perspectives, while also focusing on modernization and innovation. The scope of the Meaningful Measures Framework evolves as the health care environment continues to change.[115] Consistent with the Meaningful Measures Framework, we aim to move fully to digital quality measurement by 2025. We acknowledge facilities within the various care and practice settings covered by our quality programs may be at different stages of readiness and, therefore, the timeline for achieving full digital quality measurement across our quality reporting programs may vary.

We also continue to evolve the Medicare Promoting Interoperability Program's focus on the use of certified electronic health record (EHR) technology, from an initial focus on electronic data capture to enhancing information exchange and expanding quality measurement (83 FR 41634). However, reporting data for quality measurement via EHRs remains burdensome, and our current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).[116] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

Additionally, advancements in technical standards and associated regulatory initiatives to improve interoperability of healthcare data are creating an opportunity to significantly improve our quality measurement systems. In May 2020, we finalized interoperability requirements in the CMS Interoperability and Patient Access final rule (85 FR 25510) to support beneficiary access to data held by certain payers. At the same time, the Office of the National Coordinator for Health Information Technology (ONC) finalized policies in the ONC 21st Century Cures Act final rule (85 FR 25642) to advance the interoperability of health information technology (IT) as defined in section 4003 of the 21st Century Cures Act, including the ''complete access, exchange, and use of all electronically accessible health information.'' Closely working with ONC, we collaboratively identified Health Level 7 (HL7®) FHIR Release 4.0.1 as the standard to support API policies in both rules. ONC, on behalf of HHS, adopted the HL7 FHIR Release 4.0.1 for APIs and related implementation specifications at 45 CFR 170.215. We believe the FHIR standard has the potential to be a more efficient and modular standard to enable APIs. We also believe this standard enables collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost. By aligning technology requirements for payers, health care facilities, and health IT developers HHS can advance an interoperable health IT infrastructure that ensures healthcare facilities and patients have access to health data when and where it is needed.

In the ONC 21st Century Cures Act final rule, ONC adopted a ''Standardized API for Patient and Population Services'' certification criterion for health IT that requires the use of FHIR Release 4 and several implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742).[117] The

[115] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[116] What are patient generated health data: *https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data.*

[117] Application Programming Interfaces (API) Resource Guide, Version 1.0. Available at: *https://www.healthit.gov/sites/default/files/page/2020-11/API-Resource-Guide_v1_0.pdf.*

ONC 21st Century Cures Act final rule also requires health IT developers to update their certified health IT to support the United States Core Data for Interoperability (USCDI) standard.[118] The scope of patient data identified in the USCDI and the data standards that support this data set are expected to evolve over time, starting with data specified in Version 1 of the USCDI. In November 2020, ONC issued an interim final rule with comment period extending the date when health IT developers must make technology meeting updated certification criteria available under the ONC Health IT Certification Program until December 31, 2022 (85 FR 70064).[119]

The CMS Interoperability and Patient Access final rule (85 FR 25510) and program policies build on the ONC 21st Century Cures Act final rule (85 FR 25642). The CMS Interoperability and Patient Access final rule and policies require certain payers (for example, Medicare Advantage organizations, Medicaid and Child Health Insurance Program (CHIP) Fee-for-Service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and issuers of certain Qualified Health Plan (QHP) on the Federally-facilitated Exchanges (FFEs)) to implement and maintain a standards-based Patient Access API using HL7 FHIR Release 4.0.1 to make available claims and encounter data to their enrollees and beneficiaries (called ''patients'' in the CMS interoperability rule) with the intent of ensuring enrollees and beneficiaries have access to their own health care information through third-party software applications.

The CMS Interoperability and Patient Access final rule also established new conditions of participation for Medicare and Medicaid participating hospitals and critical access hospitals (CAHs), requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged, or transferred (85 FR 25603).

In the calendar year (CY) 2021 Physician Fee Schedule (PFS) final rule (85 FR 84472), we finalized a policy to align the certified EHR technology required for use in the Promoting Interoperability Programs and the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category with the updates to health IT certification criteria finalized in the ONC 21st Century Cures Act final rule. Under this policy, MIPS eligible clinicians, and eligible hospitals and CAHs participating in the Promoting Interoperability Programs, must use technology meeting the updated certification criteria for performance and reporting periods beginning in 2023 (85 FR 84825).

The use of APIs can also reduce long-standing barriers to quality measurement. Currently, health IT developers are required to implement individual measure specifications within their health IT products. The health IT developer must also accommodate how that product connects with the unique variety of systems within a specific care setting.[120] This may be further complicated by systems that integrate a wide range of data schemas. This process is burdensome and costly, and it is difficult to reliably obtain high quality data across systems. As health IT developers map their health IT data to the FHIR standard and related implementation specifications, APIs can enable these structured data to be easily accessible for quality measurement or other use cases, such as care coordination, clinical decision support, and supporting patient access.

We believe the emerging data standardization and interoperability enabled by APIs will support the transition to full digital quality measurement by 2025, and are committed to exploring and seeking input on potential solutions for the transition to digital quality measurement as described in this RFI.

B. Definition of Digital Quality Measures

In this section we seek to refine the definition of digital quality measures (dQMs) to further operationalize our objective of fully transitioning to dQMs by 2025. We previously noted dQMs use ''sources of health information that are captured and can be transmitted electronically and via interoperable systems'' (85 FR 84845). In this RFI, we seek input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. We also note that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs. We discuss one potential approach to developing dQM software in section XIV.D.2. of the preamble of this proposed rule. In this section, we are seeking comment on the potential definition of dQMs in this RFI.

We also seek feedback on how leveraging advances in technology (for example, FHIR-based APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement (for example, the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements).

The transition to dQMs relies on advances in data standardization and interoperability. As providers and payers work to implement the required advances in interoperability over the next several years, we will continue to support reporting of eCQMs through CMS quality reporting programs and through the Promoting Interoperability Programs.[121] These fully digital measures continue to be important drivers of interoperability advancement and learning. As discussed in the next section, we are currently re-specifying and testing these measures to use FHIR rather than the currently adopted Quality Data Model (QDM) in anticipation of the wider use of FHIR standards. CMS intends to apply significant components of the output of this work, such as the re-specified measure logic and the learning done through measure testing with FHIR-based APIs, to define and build future dQMs that take advantage of the expansion of standardized, interoperable data.

C. Use of FHIR for Current eCQMs

Since we adopted eCQMs in our hospital and clinician quality programs, we have heard from stakeholders about the technological challenges, burden, and related costs of reporting eCQM data. The CMS eCQM Strategy Project engaged with stakeholders through site visits and listening sessions with health

[118] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[119] Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the Covid-19 Public Health Emergency. Available at: *https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24376.pdf.*

[120] The Office of the National Coordinator for Health Information Technology, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Final Report (Feb. 2020). Available at: *https://www.healthit.gov/sites/default/files/page/2020–02/BurdenReport_0.pdf.*

[121] eCQI Resource Center. Available at: *https://ecqi.healthit.gov/.*

systems and provider organizations to learn about their experiences. This stakeholder feedback identified recommendations to improve processes related to alignment; development; implementation and reporting; certification; and communication, education, and outreach. Over the past 2 years, we have focused on opportunities to streamline and modernize quality data collection and reporting processes, such as exploring FHIR (*http://hl7.org/fhir*) as a framework for measure structure and data submission for quality reporting programs, specifically for eCQMs. FHIR is a free and open source standards framework (in both commercial and government settings) created by HL7 International that establishes a common language and process for all health information technology. FHIR allows systems to communicate and information to be shared seamlessly, with a lower burden for hospitals, providers, clinicians, vendors, and quality measurement stakeholders. Specifically, for quality reporting, FHIR enables representing the data in eCQMs as well as provides a structure for eCQMs and reporting, using FHIR as the standard for all. Whereas today, multiple standards being used to report eCQMs is challenging and burdensome.

We are working to convert current eCQMs to the FHIR standard. We are currently testing the exchange of data elements represented in FHIR to CMS through ongoing HL7 Connectathons and integrated system testing by using and refining implementation guides (IGs). Submitting data through FHIR-based APIs has the potential to improve data exchange by providing consistent security, performance, scalability, and structure to all users. In addition, development of FHIR-based APIs could decrease provider burden by automating more of the measure data collection process. We continue to explore and expand potential applications of the FHIR standard and testing with eCQM use cases, and we are strongly considering a transition to FHIR-based quality reporting with the use of the FHIR standard for eCQMs in quality and value-based reporting programs. As we move to an all-dQM format for quality programs, we are depending on testing results and community readiness to improve interoperability, reduce burden, and facilitate better patient care. We will continue to consider how to leverage the interoperability advantages offered by the FHIR standards and API-based data submission, including digital quality measurement.

D. Changes Under Consideration To Advance Digital Quality Measurement: Potential Actions in Four Areas To Transition to Digital Quality Measures by 2025

Building on the advances in interoperability and learning from testing of FHIR-converted eCQMs, we aim to move fully to dQMs, originating from sources of health information that are captured and can be transmitted electronically via interoperable systems, by 2025.

To enable this transformation, we are considering further modernization of the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate.

These changes would enable us to collect and utilize more timely, actionable, and standardized data from diverse sources and care settings to improve the scope and quality of data used in quality reporting and payment programs, reduce quality reporting burden, and make results available to stakeholders in a rapid-cycle fashion. Data collection and reporting efforts would become more efficient, supported by advances in interoperability and data standardization. Aggregation of data from multiple sources would allow assessments of costs and outcomes to be measured across multiple care settings for an individual patient or clinical conditions. We believe that aggregating data for measurement can incorporate a more holistic assessment of an individual's health and health care and produce the rich set of data needed to enable patients and caregivers to make informed decisions by combining data from multiple sources (for example, patient reported data, EHR data, and claims data) for measurement.

Perhaps most importantly, these steps would help us deliver on the full promise of quality measurement and drive us toward a learning health system that transforms healthcare quality, safety, and coordination and effectively measures and achieves value-based care. The shift from a static to a learning health system hinges on the interoperability of healthcare data, and the use of standardized data. dQMs would leverage this interoperability to deliver on the promise of a learning health system wherein standards-based data sharing and analysis, rapid-cycle feedback, and quality measurement and incentives are aligned for continuous improvement in patient-centered care. Similarly, standardized, interoperable data used for measurement can also be used for other use cases, such as clinical decision support, care coordination and care decision support, which impacts health care and care quality.

We are requesting comments on four potential future actions that would enable transformation to a fully digital quality measurement enterprise by 2025.

1. Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-Based APIs

We are considering targeting the data required for our quality measures that utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data. Utilizing standardized data for EHR-based measurement (based on FHIR and associated IGs) and aligning where possible with interoperability requirements can eliminate the data collection burden providers currently experience with required chart-abstracted quality measures and reduce the burden of reporting digital quality measure results. We can fully leverage this advance to adapt eCQMs and expand to other dQMs through the adoption of interoperable standards across other digital data sources. We are considering methods and approaches to leverage the interoperability data requirements for APIs in certified health IT set by the ONC 21st Century Cures Act final rule to support modernization of CMS quality measure reporting. As discussed previously, these requirements will be included in certified technology in future years (85 FR 84825) including availability of data included in the USCDI via standards-based APIs, and CMS will require clinicians and hospitals participating in MIPS and the Promoting Interoperability Programs, respectively, to transition to use of certified technology updated consistent with the 2015 Cures Edition Update (85 FR 84825).

Digital data used for measurement could also expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs. Many important data sources are not currently captured digitally, such as survey and PGHD. We intend to work to innovate and broaden the digital data used across the quality measurement enterprise beyond the clinical EHR and administrative claims. Agreed upon

standards for these data, and associated implementation guides will be important for interoperability and quality measurement. We will consider developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, requirements for expressing data in standards, exposing data via standards-based APIs, and incentivizing technologies that innovate data capture and interoperability.

High quality data are also essential for reliable and valid measurement. Hence, in implementing the shift to collect all clinical EHR data via FHIR-based APIs, we would support efforts to strengthen and test the quality of the data obtained through FHIR-based APIs for quality measurement. We currently conduct audits of eCQM data submitted under our quality programs, including the Hospital Inpatient Quality Reporting (IQR) Program, with functions including checks for data completeness and data accuracy, confirmation of proper data formatting, alignment with standards, and appropriate data cleaning (82 FR 38398 through 38402). These functions would continue and be applied to dQMs and further expanded to automate the manual validation of the data compared to the original data source (for example, the medical record) where possible. Analytic advancements such as natural language processing, big data analytics, and artificial intelligence, can support this evolution. These techniques can be applied to validating observed patterns in data and inferences or conclusions drawn from associations, as data are received, to ensure high quality data are used for measurement.

We are seeking feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. We are also seeking feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data. We also welcome comment on approaches for testing data quality and validity.

2. Redesigning Quality Measures To Be Self-Contained Tools

We are considering approaches for including quality measures that take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. We are considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; calculate measure score(s); and produce reports. In general, we believe to optimize the use of standardized and interoperable data, the software solution for dQMs should do the following:

- Have the flexibility to support calculation of single or multiple quality measure(s).
- Perform three functions —
  - ++ Obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in the future from claims, PRO, and PGHD);
  - ++ Calculate the measure score according to measure logic; and
  - ++ Generate measure score report(s).
- Be compatible with any data source systems that implement standard interoperability requirements.
- Exist separately from digital data source(s) and respect the limitations of the functionality of those data sources.
- Be tested and updated independently of the data source systems.
- Operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange.
- Have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications.
- Be designed to enable easy installation for supplemental uses by medical professionals and other non-technical end-users, such as local calculation of quality measure scores or quality improvement.
- Have the flexibility to employ current and evolving advanced analytic approaches such as natural language processing.
- Be designed to support pro-competitive practices for development, maintenance, and implementation as well as diffusion of quality measurement and related quality improvement and clinical tools through, for example, the use of open-source core architecture.

We seek comment on these suggested functionalities and other additional functionalities that quality measure tools should ideally have particularly in the context of the possible expanding availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs).

We are also interested whether and how this more open, agile strategy may facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research.

3. Building a Pathway to Data Aggregation in Support of Quality Measurement

Using multiple sources of collected data to inform measurement would reduce data fragmentation (or, different pieces of data regarding a single patient stored in many different places). Additionally, we are considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. Qualified Clinical Data Registries and Qualified Registries that report quality measures for eligible clinicians in the MIPS program are potential examples [122] at 42 CFR 414.1440(b)(2)(iv) and (v) and (c)(2)(iii) and (iv) and can also support measure reporting. We are considering establishing similar policies for third-party aggregators to maintain the integrity of our measure reporting process and to encourage market innovation.

We seek feedback on aggregation of data from multiple sources to inform measurement and potential policy considerations. We also seek feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers, and how we can best facilitate and enable aggregation.

4. Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to solve the issue of interoperable data exchange and to transition to full digital quality measurement. We are considering the future potential development and multi-staged implementation of a common portfolio of dQMs across our regulated programs, agencies, and private payers. This common portfolio would require alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure

[122] CY 2021 Physician Fee Schedule Final Rule: Finalized (New and Updated) Qualified Clinical Data Registry (QCDR) and Qualified Registry Policies, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1362/QCDR%20and%20QR%20Updates%202021%20Final%20Rule%20Fact%20Sheet.pdf.*

specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and IGs for key data elements. We would coordinate closely with quality measure developers, Federal and state agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across Federal and state agencies and payers to the extent possible.

We intend for this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, PROs, disparities, and care coordination), and track with the transformation of data collection, alignment with health IT module updates including capabilities and standards adopted by ONC (for example, standards to enable APIs). This coordination would build on the principles outlined in HHS' National Health Quality Roadmap.[123] It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing Federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (Department of Defense and Veterans Affairs (DoD/VA)); the Agency for Healthcare Research and Quality's (AHRQ) Clinical Decision Support Initiative; the Centers for Disease Control and Prevention's (CDC) Adapting Clinical Guidelines for the Digital Age initiative; Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, National Quality Forum (NQF), provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint Federal, state, and industry effort, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements for measures as well as the requirements of other agencies and payers.

We seek feedback on initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools, and data standards). We also seek to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities across sectors.

E. Solicitation of Comments

As noted previously, we seek input on the future development of the following:

• Definition of Digital Quality Measures. We are seeking feedback on the following as described in section XIV.2. of the preamble of this proposed rule:

++ Do you have feedback on the potential future dQM definition?

++ Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcome more specific comments on the attributes or functions to support such an approach of deploying dQMs.

• Use of FHIR for Current eCQMs. We are seeking feedback on the following as described in section XIV.3. of the preamble of this proposed rule:

++ Would a transition to FHIR-based quality reporting reduce burden on health IT vendors and providers? Please explain.

++ Would access to near real-time quality measure scores benefit your practice? How so?

++ What parts of the current CMS Quality Reporting Data Architecture (QRDA) IGs cause the most burden (please explain the primary drivers of burden)?

++ In what ways could CMS FHIR Reporting IG be modified to reduce burden on providers and vendors?

• Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.

++ We are seeking feedback on the following as described in section XIV.4.a. of the preamble of this proposed rule:

—Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach? Are there specific FHIR IGs suggested for consideration?

—How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

—What are possible approaches for testing data quality and validity?

++ We are seeking feedback on the following as described in section XIV.4.b. of the preamble of this proposed rule:

—What functionalities, described in section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?

—How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?

++ We seek feedback on the following as described in section XIV.4.c. of the preamble of this proposed rule:

—What are key policy considerations for aggregation of data from multiple sources being used to inform measurement?

—What role can or should data aggregators play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

++ We seek feedback on the following as described in section XIV.4.d. of the preamble of this proposed rule:

—What are initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)?

—We also seek to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

Commenters should consider provisions in the CMS Interoperability and Patient Access final rule (85 FR

[123] Department of Health and Human Services, National Health Quality Roadmap (May 2020). Available at: *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

25510), CMS CY 2021 PFS final rule (85 FR 84472), and the ONC 21st Century Cures Act final rule (85 FR 25642).

We plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025. While we will not be responding to specific comments submitted in response to this Request for Information in the CY 2022 OPPS/ASC final rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

XV. 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.

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. The Hospital OQR Program regulations are codified at 42 CFR 419.46. In the CY 2021 OPPS/ASC final rule (85 FR 86179), we finalized to update the regulations to include a reference to the statutory authority for the Hospital OQR Program. Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual Outpatient Department (OPD) fee schedule increase factor. In the CY 2021 OPPS/ASC final rule (85 FR 86179) we codified the Hospital OQR Program's statutory authority at § 419.46(a).

3. Regulatory History of the Hospital OQR Program

We refer readers to the CY 2008 through 2021 OPPS/ASC final rules with comment period for detailed discussions of the regulatory history of the Hospital OQR Program:

- The CY 2008 OPPS/ASC final rule (72 FR 66860 through 66875);
- The CY 2009 OPPS/ASC final rule (73 FR 68758 through 68779);
- The CY 2010 OPPS/ASC final rule (74 FR 60629 through 60656);
- The CY 2011 OPPS/ASC final rule (75 FR 72064 through 72110);
- The CY 2012 OPPS/ASC final rule (76 FR 74451 through 74492);
- The CY 2013 OPPS/ASC final rule (77 FR 68467 through 68492);
- The CY 2014 OPPS/ASC final rule (78 FR 75090 through 75120);
- The CY 2015 OPPS/ASC final rule (79 FR 66940 through 66966);
- The CY 2016 OPPS/ASC final rule (80 FR 70502 through 70526);
- The CY 2017 OPPS/ASC final rule (81 FR 79753 through 79797);
- The CY 2018 OPPS/ASC final rule (82 FR 59424 through 59445);
- The CY 2019 OPPS/ASC final rule (83 FR 59080 through 59110);
- The CY 2020 OPPS/ASC final rule (84 FR 61410 through 61420); and
- The CY 2021 OPPS/ASC final rule (85 FR 86179 through 86187).

We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46. We refer readers to section XV.E. of this proposed rule for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements for the CY 2024 payment determination.

B. Hospital OQR Program Quality Measures

1. Considerations in Selecting 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. We are not proposing any changes to these policies in this proposed rule.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously finalized and codified at § 419.46(h)(1) a policy to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets, unless removed (77 FR 68471 and 83 FR 59082). We are not proposing any changes to these policies in this proposed rule.

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Immediate Removal

We previously finalized and codified at § 419.46(i)(2) and (3) a process for removal and suspension of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raises patient safety concerns (74 FR 60634 through 60635, 77 FR 68472, and 83 FR 59082).[124] We are not proposing any changes to these policies in this proposed rule.

b. Consideration Factors for Removing Measures

We previously finalized and codified at § 419.46(i)(3) policies 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 (74 FR 60635 and 83 FR 59082).[125] We are not proposing any changes to these policies in this proposed rule.

c. Proposed Removals Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination: OP–02 (Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and OP–03 (Median Time To Transfer to Another Facility for Acute Coronary Intervention)

In this proposed rule, we are proposing to remove two chart-abstracted measures under removal Factor 4—the availability of a more broadly applicable (across settings, populations, or conditions) measure for the particular topic:

- Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP–2); and
- Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3).

The OP–2 measure assesses the number of acute myocardial infarction (AMI) patients with: (a) ST-segment elevation on the electrocardiogram closest to arrival time receiving fibrinolytic therapy during the ED visit; and (b) a time from hospital arrival to fibrinolysis of 30 minutes or less. For

[124] 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.

[125] 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.

more details on this measure, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865), where this measure was designated as ED–AMI–3, and the CY 2009 OPPS/ASC final rule with comment period (73 FR 68761), where this measure was relabeled OP–2 (for the CY 2010 payment determination and subsequent years). The OP–3 measure assesses the median number of minutes before outpatients with chest pain or possible heart attack who needed specialized care were transferred to another hospital capable of offering such specialized care. For more details on this measure, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865), where this measure was designated as ED–AMI–5, and the CY 2009 OPPS/ASC final rule with comment period (73 FR 68761), where this measure was relabeled OP–3 (for the CY 2010 payment determination and subsequent years).

In this proposed rule, we are proposing to remove these two measures (Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department (ED) Arrival (OP–2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3)) beginning with the CY 2023 reporting period/CY 2025 payment determination due to the availability of a more broadly applicable measure. Specifically, in this proposed rule, we are proposing to adopt the ST-Segment Elevation Myocardial Infarction (STEMI) electronic clinical quality measure (eCQM) into the Hospital OQR Program measure set, which would serve as a replacement for these two measures. We refer readers to section XV.B.4.c. of this proposed rule for further discussion of the STEMI eCQM, including the measure overview, data sources, and measure calculation.

OP–2 and OP–3 measure the proportion of eligible STEMI patients who receive timely fibrinolytic therapy and timely transfer from an ED to another facility to receive appropriate care, respectively. The STEMI eCQM is a proposed electronic process measure that includes both the populations of OP–2 and OP–3. It measures the percentage of ED patients diagnosed with STEMI that received timely fibrinolytic therapy (within 30 minutes) or timely transfer to a percutaneous coronary intervention (PCI)-capable facility (within 45 minutes). Additionally, the STEMI eCQM captures transfer and non-transfer patients at a PCI-capable facility who receive PCI (within 90 minutes). Pursuant to removal Factor 4, we believe that the adoption of the STEMI eCQM would capture the OP–2 and OP–3 measure populations and expand beyond these populations to comprehensively measure the timeliness and appropriateness of STEMI care.

Furthermore, the OP–2 and OP–3 measures are chart-abstracted measures, which result in greater provider burden due to manual abstraction. The STEMI eCQM allows for the retrieval of data directly from the electronic health record (EHR) using patient-level data. As a result, we believe the STEMI eCQM is a more broadly applicable measure and transitions the Hospital OQR Program toward the use of EHR data for quality measurement. We note that removal of these measures is contingent on the finalization of the STEMI eCQM. We invite public comment on our proposals to remove these measures.

4. Proposals To Adopt New Measures for the Hospital OQR Program Measure Set

In this proposed rule, we are proposing to adopt three new measures: (1) COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure, beginning with the CY 2022 reporting period; (2) Breast Screening Recall Rates measure, beginning with the CY 2022 reporting period; and (3) STEMI eCQM, beginning as a voluntary measure with the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period. We refer readers to the following sections for more information.

a. Proposal To Adopt the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination

(1) Background

On January 31, 2020, the Secretary declared a public health emergency (PHE) for the United States (U.S.) in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[126] COVID–19 is a contagious respiratory infection[127] that can cause serious illness and death. Older individuals, some racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[128] [129] As of July 2, 2021, the U.S. has reported over 33 million cases of COVID–19 and over 600,000 COVID–19 deaths.[130] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[131] Between December 2, 2020 and January 30, 2021, more than 100,000 Americans with COVID–19 were hospitalized at the same time.[132]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[133] Ongoing research indicates that fully vaccinated people without immunocompromising conditions are able to engage in most activities with very low risk of acquiring or transmitting SARS–CoV–2, and the Centers for Disease Control and Prevention (CDC) issued new guidance for fully vaccinated individuals on May 28, 2021.[134] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[135] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone

[126] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[127] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[128] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[129] Centers for Disease Control and Prevention. (2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[130] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[131] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895.* Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.*

[132] US Currently Hospitalized | The COVID Tracking Project. Accessed January 31, 2021 at: *https://covidtracking.com/data/charts/us-currently-hospitalized.*

[133] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[134] Centers for Disease Control and Prevention. (2021). Interim Public Health Recommendations for Fully Vaccinated People. Accessed on June 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.*

[135] *Ibid.*

who has COVID–19.[136] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface[137] and that in certain circumstances, infection can occur through airborne transmission.[138] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed COVID–19 infection, regardless of whether the individual has symptoms.[139] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between HCP and patients or from patient to patient given the close contact that may occur during the provision of care.[140] The CDC has emphasized that health care settings, including long-term care (LTC) settings, can be high-risk places for COVID–19 exposure and transmission.[141]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[142] On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[143] Subsequently, the FDA issued EUAs for additional COVID–19 vaccines.[144] [145]

As part of its national strategy to address COVID–19, the White House stated on March 25, 2021 that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[146] On April 21, 2021, it was announced that this goal had been achieved.[147] Although the goal of the U.S. Government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, the Department of Health and Human Services (HHS), the Department of Defense (DoD), and the CDC, recommended that early vaccination efforts focus on those critical to the PHE response, including HCP, and individuals at highest risk for developing severe illness from COVID–19.[148] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity.[149] Research suggests most states followed this recommendation,[150] and HCP began receiving the vaccine in mid-December of 2020.[151]

Frontline healthcare workers, such as those employed in hospitals, have been prioritized for vaccination in most locations. There are approximately 18 million healthcare workers in the U.S.[152] A survey of HCP found that 66 percent of hospital HCP and 64 percent of outpatient clinic HCP reported receiving at least one dose of the vaccine.[153] As of July 2, 2021, the CDC reported that over 328 million doses of COVID–19 vaccine had been administered and approximately 155.9 million people were fully vaccinated.[154] The White House indicated on April 6, 2021, that the U.S. retains sufficient vaccine supply, and every adult became eligible to receive the vaccine beginning April 19, 2021.[155]

We believe it is important to require that hospital outpatient departments (HOPDs) report HCP vaccination information for health care facilities to assess whether these facilities are taking steps to limit the spread of COVID–19 among their health care workers and to help sustain the ability of HOPDs to continue serving their communities throughout the PHE and beyond. Therefore, we are proposing to adopt a new measure, COVID–19 Vaccination Coverage Among HCP, beginning with the CY 2024 payment determination. For that payment year, hospitals would be required to report data quarterly on the measure for the January 2022 through December 2022 reporting period. The measure would assess the proportion of a hospital's health care workforce that has been vaccinated against COVID–19.

HCP are at risk of transmitting COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and

[136] *Ibid.*

[137] *Ibid.*

[138] Centers for Disease Control and Prevention. (2020). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[139] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.*

[140] Centers for Disease Control and Prevention. 2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19.

[141] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[142] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[143] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download.*

[144] U.S. Food and Drug Administration. (2021). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download.*

[145] U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.*

[146] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on April 3, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/.*

[147] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 2, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/21/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations-2/.*

[148] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[149] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[150] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.*

[151] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.*

[152] Centers for Disease Control and Prevention. Healthcare Workers. (2017) Accessed February 18, 2021 at: *https://www.cdc.gov/niosh/topics/healthcare/default.html.*

[153] KFF/The Washington Post Frontline Health Care Workers Survey. (2021). Accessed June 2, 2021 at: *https://www.kff.org/coronavirus-covid-19/poll-finding/kff-washington-post-health-care-workers/.*

[154] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. COVID Data Tracker. COVID–19 Vaccinations in the United States. (2021). Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

[155] The White House. Remarks by President Biden Marking the 150 Millionth COVID–19 Vaccine Shot. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/.*

transmitting it to their families, friends, and the general public. We believe HOPDs should report the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can reduce illness that leads to work absence and limit disruptions to providing care [156] with major reductions in SARS–CoV–2 infections among those receiving two dose COVID–19 vaccine despite a high community infection rate.[157] Data from influenza vaccination demonstrates that provider vaccination is associated with that provider recommending vaccination to patients,[158] and we believe HCP COVID–19 vaccination in HOPDs could similarly increase uptake among that patient population. We also believe that publicly reporting the HCP vaccination rates would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose HOPDs for treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promote Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure (''COVID–19 HCP vaccination measure'') is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-LTC facilities including outpatient hospitals.

(a) Measure Specifications

The denominator for the HCP measure is the number of HCP eligible to work in the hospital for at least 1 day during the self-selected week, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[159]

The numerator for the HCP measure is the cumulative number of HCP eligible to work in at the hospital for at least 1 day during the self-selected week and who received a complete vaccination course against COVID–19 using an FDA-authorized or FDA-approved vaccine for COVID–19 (whether the FDA issued an approval or EUA).[160] A complete vaccination course is defined under the specific FDA authorization and may require multiple doses or regular revaccination.[161] Vaccination coverage for purposes of this measure is defined as the estimated percentage (given the potential for week-to-week variation) of HCP eligible to work at the hospital for at least 1 day who received a COVID–19 vaccine. Acute care facilities would count HCP working in all inpatient or outpatient units that are physically attached to the inpatient acute care facility site and share the same CMS certification number (CCN), regardless of the size or type of unit. Facilities would also count HCP working in inpatient and outpatient departments that are affiliated with the specific acute care facility (such as sharing medical privileges or patients), regardless of distance from the acute care facility and also share the same CCN. The decision to include or exclude HCP from the acute care facility's HCP vaccination counts would be based on whether individuals meet the specified National Healthcare Safety Network (NHSN) criteria and are physically working in a location that is considered any part of the on-site acute care facility that is being monitored.[162] The proposed specifications for the COVID–19 vaccination coverage among HCP measure is available on the NQF website at: *https://www.cdc.gov/nhsn/nqf/index.html*.[163]

(b) Review by the Measure Applications Partnership

The COVID–19 HCP vaccination measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' [164] a list of measures under consideration for use in various Medicare programs. The Measure Applications Partnership (MAP) hospital workgroup convened on January 11, 2021, and it reviewed the list of Measures Under Consideration (MUC) including the COVID–19 HCP vaccination measure. The MAP hospital workgroup agreed that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it could bring value to the Hospital OQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[165] The MAP hospital workgroup also stated in its preliminary recommendations that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to hospitals would allow hospitals to benchmark coverage rates and improve coverage in their facility, and that reducing COVID–19 infection rates in HCP may reduce transmission among patients and reduce instances of staff shortages due to illness.[166]

In its preliminary recommendations, the MAP hospital workgroup did not support this measure for rulemaking, subject to the potential for mitigation.[167] To mitigate its concerns, the MAP hospital workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and National Quality Forum (NQF) endorsement prior to implementation.[168] Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 HCP vaccination measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measure back to MAP once the specifications were further refined. The MAP specifically stated, ''the incomplete specifications require immediate mitigation and further development should continue.'' [169] In its

[156] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*.

[157] Benenson S, Oster Y, Cohen MJ, Nir-Paz R. BNT162b2 mRNA Covid–19 Vaccine Effectiveness among Health Care Workers. N Engl J Med. 2021. See also: Keehner J, Horton LE, Pfeffer MA, Longhurst CA, Schooley RT, Currier JS, et al. SARS–CoV–2 Infection after Vaccination in Health Care Workers in California. N Engl J Med. 2021.

[158] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[159] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed March 15, 2021 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications*.

[160] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[161] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[162] Centers for Disease Control and Prevention. CMS Reporting Requirements FAQs. Accessed June 2, 2021 at: *https://www.cdc.gov/nhsn/PDFs/CMS/faq/FAQs-CMS-Reporting-Requirements.pdf*.

[163] *https://www.cdc.gov/nhsn/nqf/index.html*.

[164] The National Quality Forum. (2021) Accessed March 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[165] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[166] *Ibid*.

[167] *Ibid*.

[168] *Ibid*.

[169] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

final report, the MAP noted that the measure would add value by providing visibility into an important intervention to limit COVID–19 infections in HCP and the patients for whom they provide care.[170] The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.[171] In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with the MAP Coordinating Committee on March 15, 2021. Additional information was provided to address vaccine availability, alignment of the COVID–19 HCP vaccination measure as closely as possible with the data collection for the Influenza HCP vaccination measure (NQF #0431), and clarification related to how HCP are defined. CMS and the CDC also presented preliminary findings from the testing of the numerator of the COVID–19 HCP vaccination measure, which is currently in process. These preliminary findings show numerator data should be feasible to collect and reliable. Testing of the measure numerator (the number of HCP vaccinated) involves a comparison of the data collected through the NHSN and independently reported through the Federal pharmacy partnership program for delivering vaccination to LTC facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination, the number of healthcare workers vaccinated in approximately 1,200 facilities for which data from both systems was available, the number of healthcare personnel vaccinated was highly correlated between the two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[172] Because of the high correlation across a large number of facilities and high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we believe the measure is feasible and reliable for use in HOPDs. After reviewing this additional information, the MAP retained its final recommendation of conditional support, and expressed support for CMS' efforts to use the measure as part of the solution for the COVID–19 public health crisis.[173]

Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting certain quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as possible to address the urgency of the COVID–19 PHE and its impact on high risk populations, including hospitals. CMS continues to engage with the MAP to mitigate concerns and appreciates the MAP's conditional support for the measure.

(c) Measure Endorsement

Under section 1833(t)(17)(C)(i) of the Act, unless the exception of subclause (ii) applies, measures selected for the quality reporting program must have been set forth by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. Under section 1833(t)(17)(C)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as we have noted in previous rulemaking (for example, 75 FR 72065 and 76 FR 74494 for the Hospital OQR and ASCQR Programs, respectively), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

The proposed COVID–19 HCP vaccination measure is not NQF endorsed and has not been submitted to NQF for endorsement consideration. We will consider the potential for future NQF endorsement as part of its ongoing work with the MAP.

Because this measure is not NQF-endorsed, we considered whether there are other available measures that assess COVID–19 vaccination rates among HCP. We found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP.

(d) Data Collection, Submission, and Reporting

Given the time sensitive nature of this measure considering the current PHE, we are proposing that hospitals would be required to begin reporting data on the proposed COVID–19 HCP vaccination measure beginning January 1, 2022, for the CY 2024 payment determination for the Hospital OQR Program. Thereafter, we propose quarterly reporting periods. While we considered annual reporting periods for the Hospital OQR Program, we are proposing quarterly reporting periods given the immediacy of the PHE and the importance of alignment across quality payment programs proposing this measure.

If our proposal to adopt this measure is finalized, hospitals would report the measure through the CDC's NHSN web-based surveillance system.[174] While the Hospital OQR Program does not currently require use of the NHSN web-based surveillance system, we have previously required use of this system for submitting data. We refer readers to the CY 2014 OPPS/ASC final rule with comment period in which we adopted the Influenza Vaccination Coverage Among Health Care Personnel (NQF #0431) measure (78 FR 75096 through 75099) and section XV.D.5.b.(1). of this proposed rule for additional information on reporting through the NHSN web-based surveillance system under the Hospital OQR Program. Hospitals also have experience reporting acute care hospital measures to the CDC's NHSN under the Hospital IQR Program.

To report this measure, we are proposing that hospitals would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one, self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet Hospital OQR Program requirements. While we believe that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that hospitals would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a hospital's

[170] *Ibid.*

[171] *Ibid.*

[172] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[173] *Ibid.*

[174] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

HCP while balancing the costs of reporting. If a hospital submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we are proposing that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each hospital, which would be calculated by taking the average of the data from the three submission periods submitted by the hospital for that quarter. If finalized, CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

Hospitals would submit the number of HCP eligible to have worked at the facility during the self-selected week that the hospital reports data in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week. As previously stated, acute care facilities would count HCP working in all inpatient or outpatient units that share the same CCN, regardless of the size or type of unit.[175]

We invite public comment on our proposal.

b. Proposal To Adopt the Breast Screening Recall Rates Measure Beginning With the CY 2023 Payment Determination

(1) Background

Performing breast imaging in the outpatient setting facilitates early detection of malignancies.[176] However, performing diagnostic mammography or digital breast tomosynthesis (DBT) as a result of a false-positive screening study or other errant data has the potential to expose women to unnecessary follow-up.[177] This could result in increased prevalence of radiation-induced cancers in younger women, including those carrying related gene mutations, such as BRCA–1 and BRCA–2 [178] [179] or additional imaging and biopsies, which could lead to unnecessary procedures for women who do not have breast cancer.[180] [181] In contrast, recalling too few women for follow-up imaging may lead to delayed diagnoses, higher stages at diagnosis, and/or undetected cases of breast cancer.[182] Given the potential negative consequences associated with too many or too few diagnostic mammography and DBT studies performed within the population, evidence from the clinical literature suggests appropriate recall rates should fall between 5 to 12 percent.[183] [184]

To address the health and clinical risks associated with too many or too few breast screening recalls, we are proposing to adopt the Breast Screening Recall Rates measure beginning with the CY 2023 payment determination using a data collection period of July 1, 2020, to June 30, 2021, and then data collection periods from July 1 through June 30 of the following year starting 3 years before the applicable payment calendar year for subsequent years. We intend for this measure to move facilities toward the 5 to 12 percent range of recall rates. Facilities that are above or below the range should consider implementation of internal quality-improvement procedures to ensure they are not missing cases or recalling individuals unnecessarily. This measure would fill the gap in women's health and oncology care that was left in the Hospital OQR Program portfolio following the removal of the Mammography Follow Up Rates measure (OP–9).[185] More specifically, this measure would directly address the reason OP–9 was removed from the Hospital OQR Program by bringing the measure into alignment with current clinical practice and emerging scientific evidence through the addition of screening and diagnostic DBT (83 FR 59096).[186] [187] [188] [189] [190] [191] [192] [193] The Breast Screening Recall Rates measure would be added to a measure set focused on imaging efficiency. While this measure, as currently specified, would not provide data on outcomes (that is, the number of patients who were recalled and subsequently diagnosed with cancer), it would give

[175] *Ibid.*

[176] Coleman, C. (2017). Early detection and screening for breast cancer. Seminars in Oncology Nursing, 33(2), 141–155. *http://dx.doi.org/10.1016/j.soncn.2017.02.009.*

[177] Bernardi D., Li T., Pellegrini M., Macaskill, P., Valentini, M., Fanto, C., Ostillo, L., & Houssami, N. (2018). Effect of integrating digital breast tomosynthesis (3D-mammography) with acquired or synthetic 2D-mammography on radiologists' true positive and false-positive detection in a population screening trial: A descriptive study. European Journal of Radiology, 106, 26–31.

[178] Berrington de Gonzalez, A., Berg, C.D., Visvanathan, K., & Robson, M. (2009). Estimated risk of radiation-induced breast cancer from mammographic screening for young BRCA mutation carriers. Journal of the National Cancer Institute, 101(3), 205–209. *https://doi.org/10.1093/jnci/djn440.*

[179] Miglioretti, D.L., Lange, J., van den Broek, J. J., Lee, C.I., van Ravesteyn, N.T., Ritley, D., Kerlikowske, K., Fenton, J.J., Melnikow, J., de Koning, H.J., & Hubbard, R.A. (2016). Radiation-induced breast cancer incidence and mortality from digital mammography screening: a modeling study. Annals of internal medicine, 164(4), 205–214. *https://doi.org/10.7326/M15-1241.*

[180] Long, H., Brooks, J.M., Harvie, M., Maxwell, A., & French, D.P. (2019). How do women experience a false-positive test result from breast screening? A systematic review and thematic synthesis of qualitative studies. British journal of cancer, 121(4), 351–358. *https://doi.org/10.1038/s41416-019-0524-4.*

[181] Nelson, H.D., Pappas, M., Cantor, A., Griffin, J., Daeges, M., & Humphrey, L. (2016). Harms of breast cancer screening: systematic review to update the 2009 U.S. preventive services task force recommendation. *Annals of internal medicine, 164*(4), 256–267. *https://doi.org/10.7326/M15-0970.*

[182] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

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[185] CMS finalized OP–9 for removal from the Hospital OQR Program in the CY 2019 Outpatient Payment Prospective System and Ambulatory Surgical Center Payment System final rule (CMS–1695–FC) (83 FR 58818).

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facilities information to use in examining their own imaging practices. Results from the measure could be used to identify opportunities for improving the efficiency and quality of care provided and would be added to a measure set focused on imaging efficiency.

(2) Overview of Measure

This claims-based process measure documents breast screening recall rates at the facility level. The Breast Screening Recall Rates measure would calculate the percentage of Medicare fee-for-service (FFS) beneficiaries for whom a traditional mammography or DBT screening study was performed that was then followed by a diagnostic mammography, DBT, ultrasound of the breast, or magnetic resonance imaging (MRI) of the breast in an outpatient or office setting on the same day or within 45 calendar days of the index image. In assessing this measure based on clinical quality and efficiency, there are potential negative consequences of high and low mammography and DBT recall rates. A middle-range number is the ideal value for this measure. A high cumulative dose of low-energy radiation can be a consequence of too many false-positive mammography and DBT recall studies. Alternatively, inappropriately low recall rates may lead to delayed diagnoses or undetected cases of breast cancer. The inclusion of DBT in evaluating recall care may improve recall rates and positive predictive values compared to metrics that focus solely on mammography.

Although this measure is not based on a specific clinical guidelines, expert clinical consensus and support from publications in the peer-reviewed literature emphasize the importance of appropriate recall rates.[194] [195] The adoption of this measure could potentially fill a gap in breast screening measures for the Hospital OQR Program. This measure would address the Meaningful Measure priority area of ''Making Care Safer.'' The measure addresses this Meaningful Measure area by: (1) Promoting appropriate use of breast cancer screening and diagnostic imaging by encouraging facilities to aim for a performance score within the target recall range; (2) reducing the harms associated with too many recalls, which can lead to unnecessary radiation exposure, anxiety and distress, and increased costs or resource utilization;[196] [197] and (3) addressing the issue of inappropriately low recall rates, which may lead to delayed diagnoses, diagnoses at a later stage, or undetected cases of breast cancer.[198]

The measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' a list of measures under consideration for use in various Medicare programs.[199] In January 2021, the Breast Screening Recall Rates measure was reviewed by both the MAP's rural health workgroup and hospital workgroup, overseen by the Coordinating Committee (MUC20–0005).[200] Both groups and the Coordinating Committee voted to conditionally support the measure, pending NQF endorsement.[201] Concerns cited during the January 2021 MAP review included: (1) The proposed recall range is not based on clinical practice guidelines, but rather expert consensus and synthesis of findings from the scientific literature; (2) use of a range (as opposed to a targeted high or low value) may be difficult for clinicians, patients, and other stakeholders to interpret; (3) the measure does not address social determinants of health, which may impact the rate of recall at some facilities; and (4) the measure does not provide complementary information about patient outcomes (for example, breast cancer detection rate), which could aid in the interpretation and usefulness of the measure's data.[202] Despite these concerns, some members of the rural health workgroup, hospital workgroup, and Coordinating Committee expressed support of the Breast Screening Recall Rates measure and noted that feedback provided by the MAP did not preclude measure implementation, given its importance to the clinical community and the public.[203] As a part of measure implementation, we would develop a suite of education and outreach materials to aid stakeholders in the interpretation of measure performance data. These materials would explain the measure structure (including use of a range representing ideal performance) to ensure stakeholders understand values within and outside of the target range. Once implemented, the measure would be re-evaluated annually, which would include a consideration of changes to the evidence base and potential integration of social determinants of health (that is, stratification or risk adjustment); updates to the measure specifications would be made iteratively, as appropriate, on an annual basis.

Section 1833(t)(17)(C)(i) of the Act authorizes the Secretary to specify a measure for addition to a program that is not endorsed by the NQF, as long as due consideration is given to other measures that have been endorsed or adopted by a consensus organization (for example, NQF). We have reviewed those NQF-endorsed measures that are related to breast imaging and have not identified any that focus on recall rates specifically. As such, we are proposing to adopt this measure for use in the Hospital OQR Program because of its importance to women's health and its ability to fill a gap in CMS' Meaningful Measure portfolio even though it has not yet been reviewed by NQF. Submission for NQF endorsement would be considered for this measure in the future.

[194] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

[195] D'Orsi, C.J., Sickles, E.A., Mendelson, E.B., Morris EA, et al. (2013). ACR BI–RADS® atlas, breast imaging reporting and data system. Reston, VA: American College of Radiology.

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[197] Nelson, H.D., Pappas, M., Cantor, A., Griffin, J., Daeges, M., & Humphrey, L. (2016). Harms of breast cancer screening: Systematic review to update the 2009 U.S. preventive services task force recommendation. *Annals of internal medicine, 164*(4), 256–267. *https://doi.org/10.7326/M15-0970.*

[198] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

[199] The National Quality Forum. ''List of Measures Under Consideration for December 21, 2020''. (2020) Accessed May 14, 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212.*

[200] The National Quality Forum. ''List of Measures Under Consideration for December 21, 2020''. (2020) Accessed May 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212.*

[201] Measure Applications Partnership. 2020–2021 Measure Applications Partnership. 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on May 14, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[202] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[203] Measure Applications Partnership. 2020–2021 Measure Applications Partnership. 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on May 14, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

(3) Measure Calculation

This claims-based process measure documents breast screening recall rates at the facility level. The Breast Screening Recall Rates measure would calculate the percentage of Medicare FFS beneficiaries for whom a traditional mammography or DBT screening study was performed that was then followed by a diagnostic mammography, DBT, ultrasound of the breast, or MRI of the breast in an outpatient or office setting on the same day or within 45 days of the index image. Specifically, the measure denominator includes Medicare FFS beneficiaries who received a screening mammography or DBT study at a facility paid under the OPPS. The numerator consists of individuals from the denominator who had a diagnostic mammography study, DBT, ultrasound of the breast, or MRI of the breast following a screening mammography or DBT study on the same day or within 45 days of the screening study. The Breast Screening Recall Rates measure does not have any exclusions. This measure is not risk adjusted. As a process-of-care measure, the decision to image a beneficiary should not be influenced by sociodemographic status factors; rather, risk adjustment for such sociodemographic factors could potentially mask important inequities in care delivery for beneficiaries seen at facilities providing data for this measure. If performance scores for this measure vary across populations, this may be reflective of differences in the quality of care provided to the diverse populations included in the measure's denominator.

Although this measure is not based on a specific clinical guideline, expert clinical consensus and support from the peer-reviewed literature emphasize the importance of appropriate recall rates.[204] We refer readers to the QualityNet website at *http://www.QualityNet.cms.gov* for the full measure specifications.

(4) Data Sources

The Breast Screening Recall Rates measure would be calculated using data from final claims that facilities submit for Medicare beneficiaries enrolled in Medicare FFS. As such, facilities would not have to submit any additional data for this measure. The measurement period for the Breast Screening Recall Rates measure is 12 months. As noted previously, we would use final claims data from July 1, 2020 to June 30, 2021 to calculate the measure for the CY 2023 payment determination and then data collection periods from July 1 through June 30 of the following year starting 3 years before the applicable payment calendar year for subsequent years. Please note that claims for the initial patient population would be identified from July 1 through May 17 of each year, with numerator cases occurring from July 1 through June 30 annually. The data would be calculated only for facilities paid under the OPPS for mammography and DBT screening in the hospital outpatient setting. Data from the hospital outpatient and carrier files would be used to determine beneficiary inclusion (for example, a mammography follow-up study can occur in any location and be eligible for inclusion in the measure's numerator).

We invite public comment on our proposal.

c. Proposal To Adopt the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM Beginning With Voluntary Reporting for the CY 2023 Reporting Period and Mandatory for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

(1) Background

An ST-segment elevation myocardial infarction (STEMI) is a form of heart attack in which there is a complete occlusion of one of the heart arteries.[205] Each year over 250,000 Americans experience a STEMI, approximately 50 percent of whom are Medicare beneficiaries.[206] [207] This is represented on the electrocardiogram as an elevation of the ST segment—the interval between ventricular depolarization and repolarization (which represents the duration of an average ventricular contraction).[208] Time is of the essence in STEMI treatment, and the prompt identification of STEMI and restoration of blood flow to the heart (reperfusion therapy) is a key determinant of health outcomes.[209] [210] [211] Primary percutaneous coronary intervention (PCI), which is the use of balloons and stents to restore blood flow, is the preferred reperfusion modality.[212] The 2013 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) guidelines recommend the initiation of PCI within 120 minutes from first medical contact (FMC).[213] Specifically, if a patient presents to a PCI-capable facility, primary PCI is recommended within 90 minutes of FMC.[214] If a patient presents to a non-PCI-capable facility, the patient should be expeditiously transported to a PCI-capable facility and receive PCI within a total of 120 minutes.[215] However, in care settings where it is not possible for a patient to receive PCI or be transferred and receive primary PCI within the 120-minute timeframe, fibrinolytic therapy (medications to dissolve blood clots and restore flow) should be administered rapidly for reperfusion in the absence of contraindications.[216] The guidelines recommend that eligible patients should receive fibrinolytic therapy within 30 minutes of hospital arrival.

(2) Overview of Measure

The STEMI eCQM measures the percentage of ED patients with a diagnosis of STEMI who received timely delivery of guideline-based reperfusion therapies appropriate for the care setting and delivered in the absence of contraindications. The Meaningful Measures Framework aims to address

[204] Nelson, H.D., Tyne, K., Naik, A., Bougatsos, C., Chan, B.K., & Humphrey, L. (2009). Screening for breast cancer: Systematic evidence review update for the U.S. Preventive Services Task Force. *Ann Intern Med,* 151(10):727–W242.

[205] Anderson JL, Morrow DA. Acute Myocardial Infarction. *New England Journal of Medicine.* 2017;376(21):2053–2064.

[206] Ward et al. Incidence of Emergency Department Visits for ST-Elevation Myocardial Infarction in a Recent 6-Year Period in the United States. Am J Cardiol. 2015 Jan 15; 115(2): 167–170.

[207] Vallabhajosyula S, Kumar V, Sundaragiri PR, et al. Influence of primary payer status on the management and outcomes of ST-segment elevation myocardial infarction in the United States. *PLoS One.* 2020;15(12):e0243810.

[208] Vogel B, Claessen BE, Arnold SV, Chan D, Cohen DJ, Giannitsis E, Gibson CM, Goto S, Katus HA, Kerneis M, Kimura T, Kunadian V, Pinto DS, Shiomi H, Spertus JA, Steg PG, Mehran R. ST-segment elevation myocardial infarction. (2019). Nature Reviews Disease Primers, 5(39). Available at *https://doi.org/10.1038/s41572-019-0090-3.*

[209] Boersma E, Maas AC, Deckers JW, Simoons ML. Early thrombolytic treatment in acute myocardial infarction: reappraisal of the golden hour. *Lancet.* 1996;348(9030):771–775.

[210] Cannon CP, Gibson CM, Lambrew CT, et al. Relationship of symptom-onset-to-balloon time and door-to-balloon time with mortality in patients undergoing angioplasty for acute myocardial infarction. *Jama.* 2000;283(22):2941–2947.

[211] McNamara RL, Wang Y, Herrin J, et al. Effect of door-to-balloon time on mortality in patients with ST-segment elevation myocardial infarction. *J Am Coll Cardiol.* 2006;47(11):2180–2186.

[212] Anderson JL, Morrow DA. Acute Myocardial Infarction. *New England Journal of Medicine.* 2017;376(21):2053–2064.

[213] O'Gara P, Kushner F, Ascheim D, Casey D, Chung M, de Lemos J, Ettinger S, Fang J, Fesmire F, Franklin B, Granger C, Krumholz H, Linderbaum J, Morrow D, Newby L, Ornato J, Ou N, Radford M, Tamis-Holland J, Tommaso C, Tracy C, Woo Y, Zhao D, Anderson J, Jacobs A, Halperin J, Albert N, Brindis R, Creager M, DeMets D, Guyton R, Hochman J, Kovacs R, Kushner F, Ohman E, Stevenson W, Yancy C. (2013). 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 127(4): e362–425. Available at *https://www.ncbi.nlm.nih.gov/pubmed/23247304.*

[214] *Ibid.*

[215] *Ibid.*

[216] *Ibid.*

issues that are most vital to delivering quality, value-based care to improve patient outcomes.[217] In alignment with the Meaningful Measures quality priority of promoting effective prevention and treatment of chronic disease, we believe this STEMI eCQM encourages timely, effective and appropriate treatment using clinical data available in certified electronic health record technology (CEHRT) and that this measure has the potential to reduce adverse health outcomes.

The measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' a list of measures under consideration for use in various Medicare programs.[218] In January 2021, the STEMI eCQM was reviewed by the MAP's rural health workgroup, hospital workgroup, and Coordinating Committee (MUC20–0004).[219] The MAP rural health workgroup conducted discussion regarding the appropriate treatment time for STEMI and how this may be impacted in rural settings due to proximity and transportation issues, especially with getting someone to a PCI-capable facility, and supported the STEMI eCQM for rural providers in the Hospital OQR Program.[220] The MAP voted to conditionally support the measure, pending NQF endorsement.[221] We note that on-site facilities can perform a PCI (if they have the capability to do so), use fibrinolysis, or they can transfer a patient to a facility that provides PCI. These three treatment scenarios are all captured by the measure, including relative treatment times (non-transfer patients receiving PCI at a PCI-capable facility within 90 minutes of arrival and patients transferred from a non-PCI-capable to a PCI-capable facility within 45 minutes).

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus building entities (for example, NQF). We also note that section 1833(t)(17) of the Act does not require that each measure we adopt for the Hospital OQR Program be endorsed by a national consensus building entity. We have reviewed and identified two related NQF-endorsed chart-abstracted measures—OP–2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) and OP–3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention).

In section XV.B.3.c. of this proposed rule, we are proposing to remove these two related chart-abstracted measures—OP–2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) and OP–3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention)—and replace them with this eCQM. The use of the STEMI eCQM measure, in lieu of the OP–2 and OP–3 measures, would eliminate the need for manual chart-abstraction. It would also broaden the group of measured STEMI patients including patients who present to and receive primary PCI at a PCI-capable facility, which is the vast majority of STEMI patients, instead of only including patients presenting to non-PCI-capable facilities and receiving either fibrinolytics or being transferred to a PCI-capable facility. The STEMI eCQM better supports compliance with the full group of STEMI patients covered in the 2013 ACCF and AHA guidelines for the management of STEMI by measuring timeliness and appropriateness of care for STEMI patients in the ED.[222] We believe that the STEMI eCQM would efficiently and comprehensively measure timeliness of STEMI care by reducing the burden on facilities currently reporting these two chart-abstracted measures, broadening the STEMI population for which performance scores could be publicly reported, and incorporating contraindications to enhance the clinical applicability of the measure. We refer readers to section XV.B.3.c. of this proposed rule for further discussion on our proposal to remove the OP–2 and OP–3 measures from the Hospital OQR Program.

As such, we are proposing to adopt the STEMI eCQM for use in the Hospital OQR Program because of its importance in measuring timely delivery of guideline-based reperfusion therapies appropriate for the care of ED patients with a diagnosis of STEMI and its ability to fill a gap in CMS' Meaningful Measure portfolio. The measure was submitted to NQF in January 2021 and is under review.

(3) Measure Calculation

The STEMI eCQM is a process measure that assesses the percentage of ED patients aged 18 years or older with a diagnosis of STEMI who received appropriate treatment. The denominator includes all ED patients 18 years or older diagnosed with STEMI who do not have contraindications to fibrinolytic, antithrombotic, and anticoagulation therapies.

The numerator includes:

- ED-based STEMI patients whose time from ED arrival to fibrinolytic therapy is 30 minutes or fewer; or
- Non-transfer ED-based STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival; or
- ED-based STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of ED arrival at a non-PCI-capable hospital.

For more information on the STEMI eCQM, we refer readers to the full measure specifications available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website, available at: *https://ecqi.healthit.gov/pre-rulemaking-eh-oqr-ecqms*.

(4) Data Sources

The proposed measure is an eCQM that uses data routinely collected through the EHR and is designed to be calculated by the hospitals' CEHRT using patient-level data and submitted to CMS. In 2020, using data from 2018, the STEMI eCQM was tested at two hospital systems (20 EDs in total) with two different EHR platforms for feasibility, validity, and reliability testing, based on the endorsement criteria outlined by NQF.[223] The

[217] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*.

[218] The National Quality Forum. (2021). List of Measures under Consideration for December 21, 2020. Accessed March 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[219] The National Quality Forum. (2021). Meeting Summary Measure Applications Partnership Rural Health Workgroup Virtual Review Meeting. Accessed on May 17, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94656*.

[220] The National Quality Forum. (2021). Measure Applications Partnership 2020–2021. Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Accessed on May 17, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94893*.

[221] *Ibid.*

[222] O'Gara P, Kushner F, Ascheim D, Casey D, Chung M, de Lemos J, Ettinger S, Fang J, Fesmire F, Franklin B, Granger C, Krumholz H, Linderbaum J, Morrow D, Newby L, Ornato J, Ou N, Radford M, Tamis-Holland J, Tommaso C, Tracy C, Woo Y, Zhao D, Anderson J, Jacobs A, Halperin J, Albert N, Brindis R, Creager M, DeMets D, Guyton R, Hochman J, Kovacs R, Kushner F, Ohman E, Stevenson W, Yancy C. (2013). 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 127(4): e362–425. Available at *https://www.ncbi.nlm.nih.gov/pubmed/23247304*.

[223] National Quality Forum. What NQF Endorsement Means. Available at: *http://https://*

Continued

feasibility testing showed that the measure is feasible and the key features of the eCQM, such as the code sets and measure logic, were readily interpreted by both sites as assessed by the feasibility scorecard and exit interviews conducted at the two sites. The validity testing results showed a wide range of agreement among data elements between the electronic and manual data extracts. Some data elements were collected but not fully interoperable within providers' EHRs. However, as hospitals and EHR vendors meet ONC requirements for interoperability under the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) and map data elements for interoperability via the FHIR-based API required by December 31, 2022 (85 FR 70075), these data elements would be accessible without special effort.

(5) Implementation

We propose to start with voluntary reporting beginning with the CY 2023 reporting period and then with mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. We believe that taking an incremental approach to implementing this measure would allow hospitals time to implement workflow changes as necessary to better prepare for submitting data and to increase familiarity with data submission with the introduction of an eCQM into the Hospital OQR Program. We refer readers to section XV.D.6. of this proposed rule for additional proposals related to eCQM data submission and reporting requirements under the Hospital OQR Program.

We invite public comment on our proposal.

5. Modifications to Previously Adopted Measures

a. Proposal To Require OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With Voluntary Reporting for the CY 2023 Reporting Period and Mandatory Reporting Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination and for Subsequent Years

We previously adopted the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) measures to assess patient experience with care following a procedure or surgery in a HOPD. These survey-based measures rate patient experience as a means for empowering patients and improving the quality of their care (82 FR 59432). For further details on these measures, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79771 through 79784), in which we adopted these measures beginning with the CY 2020 payment determination.

Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), we delayed implementation of OP–37a–e for the Hospital OQR Program beginning with the CY 2020 payment determination due to lack of sufficient operational and implementation data. At that time, we believed that our ongoing National OAS CAHPS voluntary reporting program for the survey measures, which began in January 2016 [224] and is unrelated to either the Hospital OQR Program or ASCQR Program, would provide valuable information moving forward. Specifically, we wanted to use the information from the National OAS CAHPS voluntary reporting program to: (1) Ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; (2) reaffirm the reliability of national implementation of OAS CAHPS Survey data; and (3) appropriately account for the burden associated with administering the survey in the outpatient setting of care.

In this proposed rule, we are proposing to restart the OP–37a–e measure by requiring the measure in the Hospital OQR Program beginning with the CY 2024 reporting period/CY 2026 payment determination. Specifically, for the Hospital OQR Program, we are proposing voluntary data collection and reporting beginning with the CY 2023 reporting period, followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination. As noted previously, the National OAS CAHPS voluntary reporting program is independent of the Hospital OQR Program and the ASCQR Program. This proposal is intended to make the distinction that HOPDs that voluntarily report the OAS CAHPS survey-based measures during the CY 2023 reporting period would do so as part of the Hospital OQR Program until mandatory reporting begins, if these proposals are finalized. The reporting process for HOPDs to submit OAS CAHPS data would remain unchanged for HOPDs (that is, they would not duplicate submissions to the program and National OAS CAHPS voluntary reporting program). We refer readers to section XV.D.4.b. of the preamble of this proposed rule for our related proposals regarding the form, manner, and timing for reporting the OP–37a–e survey-based measures.

Having had the opportunity during the delayed implementation to investigate the concerns about patient response rates and data reliability, we believe that patients are able to respond to OAS CAHPS survey questions, and that those responses are reliable based on our prior experiences collecting voluntary data for public reporting since CY 2016 (available at *https://data.cms.gov/provider-data/*). We reaffirm that the OAS CAHPS survey-based measures assess important aspects of care where the patient is the best or only source of information (81 FR 79771). Furthermore, in section XV.D.4.b.(1)., we are proposing additional collection modes using a web-based module (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents) for administering the survey, which would be available beginning in CY 2023 under the Hospital OQR Program and for subsequent years.[225] We believe this would address some burden concerns raised during the CY 2017 OPPS/ASC final rule with comment period (81 FR 79777) because the web-based modules would produce similar results but at lower costs of collection.[226] We also continue to believe that the benefits of this measure, such as giving patients the opportunity to compare and assess quality of care in the outpatient setting in a standardized and comparable manner, outweigh the burdens (81 FR 79778). As we stated in the CY 2018 OPPS/ASC final rule with comment period, we continue to believe that implementation of these measures will enable objective and meaningful comparisons between hospital outpatient departments (82 FR 59432)

www.qualityforum.org/Measuring_Performance/ABCs/What_NQF_Endorsement_Means.aspx.

[224] Participation in the program is open to any interested Medicare-certified Hospital Outpatient Departments (HOPDs) and free-standing ambulatory surgery centers (ASCs). More information on the National OAS CAHPS voluntary reporting program is available at: *https://oascahps.org/General-Information/National-Implementation* and *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/OAS-CAHPS.*

[225] We note that the mixed modes will be available as part of the National OAS CAHPS voluntary reporting program beginning in CY 2022.

[226] Bergeson SC, Gray J, Ehrmantraut LA, Laibson T, Hays RD. Comparing Web-based with Mail Survey Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Clinician and Group Survey. Prim Health Care. 2013;3:1000132. doi:10.4172/2167–1079.1000132.

and rating patient experience still provides important information to hospital outpatient departments and patients and enables objective and meaningful comparisons between hospital outpatient departments (82 FR 59432).

We refer readers to section XV.D.4.b. for our related proposals regarding form, manner, and timing for reporting the OP–37a–e survey-based measures. We invite public comment on our proposal.

We also refer readers to section XVI.B.4.c. of this proposed rule where we are also proposing modifications to this measure in the ASCQR Program.

b. Proposal To Require OP–31: Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536) Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75102 through 75104) we finalized the adoption of the OP–31: Cataracts: Improvement in Patient's Visual Function with 90 Days Following Cataract Surgery [227] measure beginning with the CY 2016 payment determination. This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery (78 FR 75102). The measure data consists of pre-operative and post-operative visual function surveys. The implementation of this measure has been the subject of a number of changes as discussed in this section for the proposed rule.

During the CY 2014 OPPS/ASC proposed rule, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75103). In response to those comments, we modified and finalized our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden (78 FR 75103). Specifically, we applied a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75114). With those changes, we intended to decrease burden and facilitate data reporting by allowing random sampling of cases when volume is high, instead of collecting information for all eligible patients (78 FR 75114). For further details, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75102 through 75104).

Shortly thereafter, we became concerned about the use of inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey and we were not positive about the impact the use of varying surveys might have. Therefore, we issued guidance stating that we would delay the implementation of OP–31.[228]

Subsequently, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66947 through 66948), we finalized our proposal to exclude OP–31 from the CY 2016 payment determination measure set, and for subsequent years. We proposed to exclude OP–31 for a few reasons. First, we understood it was operationally difficult for hospitals to collect and report on the measure (79 FR 66947). Notably, the results of the survey used to assess the pre-operative and post-operative visual function of the patient were not consistently shared across clinicians, making it difficult for hospitals to have knowledge of the visual function of the patient before and after surgery (79 FR 66947). Second, the concern about use of various versions of the survey persisted. Specifically, we were concerned that if physicians used different surveys to assess visual function, then the measure could produce inconsistent results (79 FR 66947). By excluding OP–31 from the measure set used for the CY 2016 payment determination and subsequent years, hospitals were excused from reporting on it. Hospitals that did not report on OP–31 for the CY 2016 payment determination were not subject to a payment reduction (79 FR 66947). In conjunction with excusing hospitals from reporting on OP–31 for the CY 2016 payment determination and subsequent years, we finalized allowing hospitals to voluntarily report OP–31 data for the CY 2015 reporting period/CY 2017 payment determination and subsequent years (79 FR 66948).

(2) Proposal To Require Hospitals Report on OP–31 Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

We now believe it is appropriate to require hospitals to report on OP–31. Our earlier concerns have been ameliorated. At this point, hospitals have had several years to familiarize themselves with OP–31, prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period/CY 2017 payment determination. We note that a small number of facilities have consistently reported data for this measure and these data have been made publicly available. As to our second concern, research indicates that using different surveys will not result in inconsistencies, as the allowable surveys are scientifically validated.[229] Research has demonstrated that of 16 different cataract surgery outcome questionnaires, all were able to detect clinically important change.[230]

Therefore, in this proposed rule, we are proposing to require reporting of the OP–31 measure beginning with the CY 2023 reporting period/CY 2025 payment determination and for subsequent years. As we stated in the CY 2014 OPPS/ASC final rule with comment period, as well as the CY 2015 OPPS/ASC final rule with comment period, and consistent with the MAP recommendation, we continue to maintain that this measure ''addresses a high-impact condition'' that is not otherwise adequately addressed in our current measure set (78 FR 75103 and 79 FR 66947, respectively). Moreover, OP–31 serves to improve patient-centered care by representing an important patient reported outcome (78 FR 75103). This measure provides opportunities for care coordination as well as direct patient feedback.

We refer readers to section XV.D.5.a. of this proposed rule for information about submitting data via a CMS web-based tool.

We invite public comment on our proposal.

[227] We note that this measure was endorsed by the NQF under NQF #1536 at the time of adoption but has subsequently had its endorsement removed.

[228] The implementation was first delayed by 3 months—from January 1, 2014 to April 1, 2014, for the CY 2016 payment determination, via guidance issued December 31, 2013. Available at: *https://qualitynet.cms.gov/outpatient/notifications8772854917*. Because of continuing concerns, on April 2, 2014, we issued additional guidance stating that we would further delay the implementation of the measure from April 1, 2014 to January 1, 2015 for the CY 2016 payment determination. Available at: *https://qualitynet.cms.gov/outpatient/notifications*.

[229] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

[230] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

6. Summary of Previously Finalized and Proposed Hospital OQR Program Measure Sets

a. Summary of Previously Finalized and Proposed Hospital OQR Program Measure Set for the CY 2023 Payment Determination

We refer readers to the CY 2021 OPPS/ASC final rule with comment period (85 FR 86180 through 86181) for a summary of the previously adopted Hospital OQR Program measure set for the CY 2023 payment determination and subsequent years. If finalized as proposed in this proposed rule, the CY 2023 payment determination and subsequent years would also include the Breast Screening Recall Rates measure.

Table 46 summarizes the previously finalized and newly proposed Hospital OQR Program measure set for the CY 2023 payment determination:

TABLE 46: Hospital OQR Program Measure Set for the CY 2023 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
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
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	Breast Screening Recall Rates**

† We note that NQF endorsement for this measure was removed.
* OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947). In this proposed rule, we are proposing mandatory reporting of this measure beginning with the CY 2023 reporting period/CY 2025 payment determination and for subsequent years.
** We note that, if adoption finalized, an OP/measure number will be assigned for this measure in the final rule.

b. Summary of Previously Finalized and Proposed Hospital OQR Program Measure Set for the CY 2024 Payment Determination

Table 47 summarizes the previously finalized and newly proposed Hospital OQR Program measure set for the CY 2024 payment determination, which includes the proposed COVID–19 Vaccination Coverage Among HCP measure:

TABLE 47: Hospital OQR Program Measure Set for the CY 2024 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
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
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	Breast Screening Recall Rates**
None	COVID-19 Vaccination Coverage Among Health Care Personnel**

† We note that NQF endorsement for this measure was removed.
* OP-31 measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947). In this proposed rule, we are proposing mandatory reporting of this measure beginning with the CY 2023 reporting period/CY 2025 payment determination and for subsequent years.
** We note that, if adoption finalized, an OP/measure number will be assigned for this measure in the final rule.

c. Summary of Previously Finalized and Proposed Hospital OQR Program Measure Set for the CY 2025 Payment Determination

Table 48 summarizes the previously finalized and newly proposed Hospital OQR Program measure set for the CY 2025 payment determination, which includes the proposed OP–39: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM and proposed removals of the OP–2 and OP–3 measures:

TABLE 48: Hospital OQR Program Measure Set for the CY 2025 Payment Determination

NQF #	Measure Name
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
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*
None	Breast Screening Recall Rates**
None	COVID-19 Vaccination Coverage Among Health Care Personnel**
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM***

† We note that NQF endorsement for this measure was removed.
* OP-37a-e measures reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433). In this proposed rule, we are proposing voluntary reporting beginning with the CY 2023 reporting period/CY 2025 payment determination; and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.
** We note that, if finalized, an OP/measure number will be assigned for this measure in the final rule.
*** The STEMI eCQM is being proposed in this proposed rule, beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and for mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. We refer readers to section XV.B.4.c. of the preamble of this proposed rule for more detail.

d. Summary of Previously Finalized and Proposed Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

Table 49 summarizes the previously finalized and newly proposed Hospital OQR Program measure set for the CY 2026 payment determination and subsequent years, which includes the proposed mandatory reporting of the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM and the proposed requirement of the OAS CAHPS measures (OP–37a–e):

TABLE 49: Hospital OQR Program Measure Set for the CY 2026 Payment Determination and Subsequent Years

NQF #	Measure Name
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
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
None	Breast Screening Recall Rates*
None	COVID-19 Vaccination Coverage Among Health Care Personnel*
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM*

† We note that NQF endorsement for this measure was removed.
* We note that, if finalized, an OP/measure number will be assigned for this measure in the final rule.

7. Hospital OQR Program Measures and Topics for Future Considerations

a. Request for Comment on Potential Adoption of Future Measures for the Hospital OQR Program

We seek to adopt a comprehensive set of quality measures for widespread use to inform decision-making regarding care and for quality improvement efforts in the hospital outpatient setting. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083 through 86110), under the OPPS we finalized the elimination of the Inpatient Only (IPO) list over a 3-year transitional period, beginning with the removal of approximately 300 primarily musculoskeletal-related services, with the list to be completely phased out by CY 2024.[231] As discussed in section IX. of this rule, we have continued to receive stakeholder requests to reconsider the elimination of the IPO list, to reevaluate services removed from the IPO list due to safety and quality concerns, and to, at a minimum, extend the timeframe for eliminating the list. After further consideration and review of the additional feedback from stakeholders, we believe that the timeframe we adopted for removing services from the IPO list does not give us a sufficient opportunity to carefully assess whether a procedure can be removed from the IPO list while still ensuring beneficiary safety. For CY 2022, we are proposing to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021, we propose to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022.

However, as technology and surgical techniques advance, services will continue to transition off of the IPO list, becoming payable in the outpatient setting. We recognize that there may be a need for more measures that inform decision-making regarding care and for quality improvement efforts, particularly focused on the behaviors of services that become newly eligible for payment in the outpatient setting. In light of this, we seek comment on potential future adoption of measures that would allow better tracking of the quality of care for services that transition from the IPO list and become eligible for payment in the outpatient setting.

Therefore, we invite public comment on the potential future adoption of measures for our consideration that address care quality in the hospital outpatient setting given the transition of procedures from inpatient settings to outpatient settings of care.

b. Request for Comment on Potential Future Adoption and Inclusion of a Hospital-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

As described in section XV.B.7.a., we are seeking comment on priorities for quality measurement in outpatient settings due to changes to the IPO procedure list (82 FR 59385 and 84 FR 61355) and the ASC covered procedures list (CPL) (84 FR 61388 and 85 FR 86146) announced in the CY 2021 OPPS/ASC final rule with comment period.

We are also requesting comment on the potential future adoption of a respecified version of a patient-reported outcome-based performance measure

[231] Centers for Medicare & Medicaid Services. (2020, December 2). CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS–1736–FC). Retrieved from *www.cms.gov/newsroom*: *https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0.*

(PRO–PM) for two such procedures—elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA), which were removed from the IPO list effective with CY 2020 and CY 2018, respectively. We recently solicited public comment on the potential future inclusion of a hospital-level Risk-Standardized Patient-Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (Hospital-level THA/TKA PRO–PM (NQF #3559)) in the FY 2022 IPPS/LTCH PPS proposed rule for the inpatient hospital setting (86 FR 25589). This measure reports the hospital-level risk-standardized improvement rate (RSIR) in patient-reported outcomes (PROs) following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older. Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning: (1) The Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients; and (2) the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk adjusted to account for differences in patient case mix. Potential non-response bias in measure scores due to the voluntary nature of PROs is incorporated in the measure calculation with stabilized inverse probability weighting based on likelihood of response.

Currently, the volume of THA and TKA procedures performed is lower among HOPDs than in the inpatient setting. Given the relatively recent removal of TKA and THA from the IPO list, we expect that the volume of THA and TKA procedures will continue to increase in HOPDs, and that significant numbers of Medicare beneficiaries 65 and older will potentially undergo these procedures in the outpatient setting in future years.

We recognize that potential future adoption and implementation of a respecified version of the THA/TKA PRO–PM in the Hospital OQR Program would require sufficient numbers of procedures for each measured HOPD to ensure a reliable measure score. Additionally, implementing a THA/TKA PRO–PM would require providers to successfully collect pre- and post-operative PRO data for each procedure. Specifically, the inpatient THA/TKA PRO–PM discussed in the FY 2022 IPPS/LTCH PPS proposed rule proposes to require a minimum of 25 cases with completed pre- and post-operative PRO data per hospital to ensure a reliable measure score. For more details on the inpatient THA/TKA PRO–PM, we refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25589) and the PROs Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure — Measure Methodology Report, available on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

We will continue to monitor the number of THA and TKA procedures in the outpatient setting and when we believe there is a sufficient number of such procedures performed in these settings to reliably measure a meaningful number of facilities, we may consider expanding the PRO–PM to these settings. We also note that, as finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79764 through 79771), the Hospital OQR Program currently includes a Hospital Visits after Hospital Outpatient Surgery (OP–36) measure using claims data, which provides facilities with important information on patient outcomes for Medicare FFS beneficiaries following surgery at HOPDs and is publicly reported on CMS' *Care Compare* website (*https://www.medicare.gov/care-compare/*). The measure calculates a facility-specific risk-standardized hospital visit ratio within 7 days of hospital outpatient surgery, and has as outcomes of interest unplanned hospital admissions, ED visits, and observation stays thereby providing valuable quality information as these procedures are increasingly conducted as outpatient surgeries.

As described in our Meaningful Measures 2.0 Framework, we aim to promote better collection and integration of patients' voices by developing PRO measures as an additional tool for measuring and improving quality. Given the unique challenges and opportunities for PRO–PMs for THA and TKA procedures in the outpatient setting, we invite public comment on the potential future adoption of a respecified version of PRO measures for elective THA/TKA PRO–PM for the Hospital OQR Program. Specifically, we invite public comment on the following:

- Input on the mechanism of PRO data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Usefulness of having an aligned set of PRO–PMs across settings where elective THA/TKA are performed, that is, hospital inpatient setting, hospital outpatient departments, and ASCs for patients, providers, and other stakeholders. Specifically, usefulness and considerations for a hospital that performs both inpatient and outpatient elective THA/TKAs.
- Considerations unique to THA/TKAs performed in the hospital outpatient setting such as the volume of procedures performed or the measure cohort, outcome, or risk adjustment approach.

c. Request for Comment on Potential Future Efforts To Address Health Equity in the Hospital OQR Program

(1) Introduction and Expansion of the CMS Disparity Methods to Hospital OQR Program Setting

Significant and persistent inequities in health care outcomes exist in the U.S.[232] Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; and being near or below the poverty level, are often associated with worse health outcomes.[233 234 235 236 237 238 239 240] Such disparities in health outcomes are the

[232] United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*.

[233] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[234] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[235] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[236] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[237] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf*.

[238] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf*.

[239] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm*.

[240] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv*. 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

result of number of factors, including social, economic, and environmental factors, but importantly for CMS programs, although not the sole determinant, negative experiences, poor access, and provision of lower quality health care can contribute to health inequities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[241] [242] [243] [244] [245] [246] Readmission rates for common conditions in the Hospital Readmissions Reduction Program (HRRP) are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with congestive heart failure and acute myocardial infarction.[247] [248] [249] [250] [251] Studies have also shown that African Americans are significantly more likely than White Americans to die prematurely from heart disease and stroke.[252] The COVID–19 pandemic has further highlighted many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to White persons.[253] [254] As noted by the CDC, ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.'' [255] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care inequities.[256] For the purposes of this proposed rule, we are using a definition of equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQ+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [257] We note that this definition was recently established and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Network Quality Improvement Organizations (QIN–QIOs); Federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[258]

We refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070) which summarizes our existing initiatives aimed at closing the equity gap in outcomes for Medicare beneficiaries, including the CMS Disparity Methods. The methods were finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42496 through 42500), and results are currently reported confidentially across six quality measures in the HRRP stratified by dual eligibility status. As described in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070), we are considering further expanding the confidential reporting to include measurement of racial and ethnic disparities for one measure in the Hospital IQR Program, the Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789).

We have developed two complementary disparity methods to report stratified measure results for outcome measures. The first method (the Within-Hospital Disparity Method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also allows for a comparison of the magnitude of disparity across hospitals at a given point in time, so hospitals could assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital Disparity Method) is complementary to the first method and assesses hospitals' outcome rates for patients with a given risk factor, across facilities, allowing for a comparison among hospitals on their performance caring for their patients with social risk

[241] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[242] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[243] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[244] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[245] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[246] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[247] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[248] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[249] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[250] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[251] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[252] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[253] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[254] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[255] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[256] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[257] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[258] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

factors. These methods were first confidentially reported for the inpatient setting in 2019 for the Pneumonia Readmission (NQF #0506) and Pneumonia Mortality (NQF #0468) measures, stratified dual eligibility for Medicare and Medicaid, and confidential reporting for hospitals has since expanded to include additional measures. For additional information on the two disparity methods, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the 2020 Disparity Methods Updates and Specifications Report.[259] As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41599) and the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070), the two disparity methods do not place any additional collection or reporting burden on hospitals because social risk factor data are readily available in claims data.

In this proposed rule, we are seeking comment on expanding our efforts to provide results of the disparity methods to promote health equity and improve healthcare quality. Specifically, we are seeking comment on the idea of stratifying the performance results in the hospital outpatient setting. We have identified six priority measures included in the Hospital OQR Program as candidate measures for disparities reporting stratified by dual eligibility:

- MRI Lumbar Spine for Low Back Pain (OP–8);
- Abdomen CT—Use of Contract Material (OP–10);
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (OP–13);
- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP–32);
- Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP–35); and
- Hospital Visits after Hospital Outpatient Surgery (OP–36).

To identify these measures, we considered evidence of existing disparities, procedure volume, and statistical reliability. For more information about these measures, we refer readers to the Hospital Outpatient Quality Reporting Specifications Manual available on the QualityNet website.[260] We are seeking public comment on potential future confidential reporting of the six aforementioned measures, as well as other potential measures described in section XV.B.4., stratified by dual eligibility status, if technically feasible, adequately representative, and statistically reliable.

(2) Additional Social Risk Factors

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.[261] As we described earlier, we have been considering, among other things, expanding our efforts to stratify data by additional social risk factors and demographic variables, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. Following potential confidential reporting using dual eligibility as an indicator of social risk, we are exploring the possibility of further expanding stratified reporting to include race and ethnicity.

We refer readers to the ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' section of the FY 2022 IPPS/LTCH PPS proposed rule which summarizes the existing challenges in accurately determining race and ethnicity in our administrative data, and the need for using advanced statistical methods for enhancing the accuracy of race and ethnicity disparity estimates (86 FR 25554).

As we stated in the ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' section of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25554), because development of sustainable and consistent programs to collect demographic information related to health disparities, such as race and ethnicity, can be considerable undertakings, we recognize that another method to identify more accurate race and ethnicity disparities is needed in the short term. In working with our contractors, two algorithms have been developed to indirectly estimate the race and ethnicity of Medicare beneficiaries (as described further in the next section). We believe that using indirect estimation can help to overcome some of the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirectly estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on facilities as these data are derived using existing administrative and census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available. Indirectly estimated data are most commonly used at the population level (such as the hospital or health plan-level) where aggregated results form a more accurate description of the population than existing, imperfect data sets. For missing race and ethnicity information, these methods use a combination of other data sources which estimate self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.[262]

As described previously, we have previously supported the development of two such methods of indirect estimation of race and ethnicity of Medicare beneficiaries. One indirect estimation approach developed by our contractor uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, state of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or Asian/Pacific Islander (API).[263] In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census data,

[259] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

[260] *https://qualitynet.cms.gov/outpatient/specifications-manuals.*

[261] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[262] Institute of Medicine. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press. Available at: *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

[263] Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

applying both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of the six racial/ethnic groups.[264]

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C & D performance data for Medicare Advantage Plans by race and ethnicity.[265] Validation testing reveals concordances between 0.88–0.95 between indirectly estimated and self-reported race and ethnicity among those who identify as White, Black, Hispanic, and API for the MBISG version 2.0 and concordances with self-reported race and ethnicity of 0.96–0.99 for these same groups for MBISG version 2.1.[266] [267] The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial.[268] Indirect estimation is a statistically reliable approach for calculating aggregate results for groups of individuals (such as the facility-level) and is not intended, nor being considered, as an approach for predicting the race and ethnicity of individuals.

Despite the high degree of accuracy of the indirect estimation algorithms under consideration there remains the small risk of introducing measurement bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We believe this risk of bias is considerably less than would be expected if stratified reporting were conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for improving demographic data collection to progress. We are interested in learning more about, and soliciting comments about, the potential benefits and challenges associated with measuring facility equity using indirect estimation to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

(a) Improving Demographic Data Collection

Stratified facility-level reporting using indirectly estimated race and ethnicity would represent an important advance in our ability to provide accurate equity reports to facilities. However, self-reported race and ethnicity data remain the gold standard for classifying an individual according to race or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.[269] Collection and sharing of a standardized set of social, psychological, and behavioral data by hospitals, including race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.[270] This could potentially include expansion of stratified reporting to additional social risk factors, such as language preference and disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering demographic questions, and that individual preferences for non-response are maintained.

We note that facilities participating in the Medicare Promoting Interoperability Program must use CEHRT that has been certified to the 2015 Edition of health IT certification criteria as defined at 45 CFR 170.102. As noted earlier, the certification criterion for Demographics under the 2015 Edition (45 CFR 170.315(a)(5)) supports collection of data using both the OMB standards for collecting data on race and ethnicity as well as the more granular ''Race & Ethnicity—CDC'' standard. In the 2020 ONC 21st Century Cures Act final rule, ONC also adopted a new framework for the core data set which certified health IT products must exchange, called the USCDI (85 FR 25669). The USCDI incorporates the demographic data and associated code sets finalized for the 2015 Edition certification criteria.

As noted previously, ONC also finalized a certification criterion in the 2015 Edition which supports a certified health IT product's ability to collect social, psychological, and behavioral data (45 FR 170.315(a)(15)). However, this functionality is not included as part of the CEHRT required by the Medicare Promoting Interoperability Program. While the technical functionality exists to achieve the gold standard of data collection, we understand challenges and barriers exist in using the technologies with these capabilities.

We are interested in learning about and soliciting comments on current data collection practices by facilities to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, and disability status). Further, we are interested in potential challenges facing facility collection, on the day of service, of a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act [271]) and standards for interoperable exchange (such as the USCDI incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria [272]). Advancing data interoperability through collection of a minimum set of demographic data collection, and incorporation into quality measure specifications, has the potential for improving the robustness of the disparity method results, potentially permitting reporting using more accurate, self-reported information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

[264] Haas, A, Elliott, MN, Dembosky, JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019; 54: 13–23. *https://doi.org/10.1111/1475-6773.13099.*

[265] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[266] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[267] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[268] Haas, A, Elliott, MN, Dembosky, JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019; 54: 13– 23. *https://doi.org/10.1111/1475-6773.13099.*

[269] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[270] The Office of the National Coordinator for Health Information Technology. United State Core Data for Interoperability Draft Version 2. 2021. Available at: *https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf.*

[271] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[272] *https://www.healthit.gov/sites/default/files/2020-08/2015EdCures_Update_CCG_USCDI.pdf.*

(b) Solicitation of Public Comments

We are currently seeking comment on the possibility of expanding our current disparities methods to include reporting by race and ethnicity using indirect estimation. We are also seeking comment on the possibility of facility collection of standardized demographic information for the purposes of potential future quality reporting and measure stratification to permit more robust equity measurement. Additionally, we are seeking comment on the design of a Facility Equity Score for presenting combined results across multiple social risk factors and measures, including race/ethnicity and disability. Any data pertaining to these areas that are recommended for collection for measure reporting for a CMS program and potential public disclosure on *Care Compare* or successor website would be addressed through a separate and future notice-and-comment rulemaking. We plan to continue working with the Office of the Assistant Secretary for Planning and Evaluation, facilities, 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.

Specifically, we are inviting public comment on the following:

- The potential future application to the Hospital OQR Program measures of the two disparity methods currently used to confidentially report stratified measures in HRRP.
- The possibility of reporting stratified results confidentially in Facility-Specific Reports (FSRs) using dual eligibility as a proxy for social risk.
- The possibility of reporting stratified results using dual eligibility as the proxy for social risk publicly on *Care Compare* in future years.
- The potential future application of an algorithm to indirectly estimate race and ethnicity to permit stratification of measures (in addition to dual-eligibility) for facility-level disparity reporting until more accurate forms of self-identified demographic information are available.
- The possibility of facility collection, on the day of service, of a minimum set of demographic data using standardized and interoperable electronic health record standards.

8. 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://qualitynet.cms.gov/outpatient/specifications-manuals*. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59104 through 59105), where we changed the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and subsequent years, such that we will release a manual once every 12 months and release addenda as necessary. We are not proposing any changes to these policies in this proposed rule.

In section XV.B.4. of this proposed rule, we are proposing the adoption of eCQMs into the Hospital OQR Program measure set beginning with the CY 2023 reporting period. Therefore, we are also proposing the manner to update the technical specifications for eCQMs. We propose that the technical specifications for eCQMs used in the Hospital OQR Program would be contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). The Annual Update and implementation guidance documents are available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/*. For eCQMs, we would generally update the measure specifications on an annual basis through the Annual Update which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and EHR vendors to use in order to collect and submit data on eCQMs from hospital EHRs.

Hospitals would be required to register and submit quality data through the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal). The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E, for more information. We invite public comment on our proposal.

We also refer readers to section XIV. of this proposed rule where we request information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard (as described in that section).

9. Public Display of Quality Measures

a. Background

We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules with comment period (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures. We are not proposing any changes to these policies in this proposed rule.

b. Overall Hospital Quality Star Rating

In the CY 2021 OPPS/ASC final rule (85 FR 86182), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Rating). We refer readers to section XVI. (''Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years'') of the CY 2021 OPPS/ASC final rule with comment period for details. We are not proposing any changes to this policy in this proposed rule.

C. Administrative Requirements

1. QualityNet Account and Security Administrator/Security Official

a. Background

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). We codified these procedural requirements at § 419.46(b) in that final rule with comment period. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86182), we finalized to use the term ''security official'' instead of ''security administrator'' to denote the exercise of authority invested in the role. The term ''security official'' would refer to ''the individual(s)'' who have responsibilities for security and account management requirements for a hospital's QualityNet account. This update in terminology did not change the individual's responsibilities or add burden. We are not proposing any changes to this policy.

b. Active Security Official Account and Maintenance Requirements for Data Submission

The previously finalized QualityNet security administrator (now referred to as a security official) requirements, including those for 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 the CY 2011 OPPS/ASC final rule with comment period (75 FR 72099) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74479), we indicated that hospitals would be required to maintain a current QualityNet security administrator (now referred to as a security official) for as long as the hospital participates in the Program. In this proposed rule, we are clarifying that failing to maintain an active QualityNet security official once a hospital has successfully registered to participate in the Hospital OQR Program will not result in a finding that the hospital did not successfully participate in the Hospital OQR Program. Again, we refer readers to requirements at § 419.46(b).

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519), and the CY 2019 OPPS/ASC final rule with comment period (83 FR 59103 through 59104) for requirements for participation and withdrawal from the Hospital OQR Program. We codified these requirements at § 419.46(b) and (c). We are not proposing any changes to these policies in this proposed rule.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to the CYs 2014, 2016, and 2018 OPPS/ASC final rules with comment period (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439, respectively) where we finalized our policies for clinical data submission deadlines. We codified these submission requirements at § 419.46(d). The clinical data submission deadlines for the CY 2024 payment determination are illustrated in Table 50.

TABLE 50: CY 2024 Payment Determination*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2022 (April 1 - June 30)	11/1/2022
Q3 2022 (July 1 – September 30)	2/1/2023
Q4 2022 (October 1 - December 31)	5/1/2023
Q1 2023 (January 1 - March 31)	8/1/2023

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

We are not proposing any changes to these policies in this proposed rule.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2024 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. We are not proposing any changes to these policies in this proposed rule.

The following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2023 payment determination and subsequent years:

- OP–2: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);[273]
- OP–3: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);[274]
- 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).

3. Claims-Based Measure Data Requirements for the CY 2024 Payment Determination and Subsequent Years

Currently, in addition to the proposed Breast Screening Recall Rates measure, the following previously finalized Hospital OQR Program claims-based measures are required for the CY 2023 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;
- OP–36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687); and
- Breast Screening Recall Rates.[275]

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59106 through 59107), where we established a 3-year reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination and for subsequent years. In that final rule with comment period (83 FR 59136 through 59138), we established a similar policy under the ASCQR Program. We are not proposing any changes to these policies in this proposed rule. We refer readers to section XV.B.4.b. of this proposed rule where we are also proposing a 3-year reporting period for the Breast Screening Recall Rates measure.

[273] In this year's proposed rule we are proposing to remove OP–2 beginning with the CY 2023 reporting period/CY 2025 payment determination.

[274] In this year's proposed rule we are proposing to remove OP–3 beginning with the CY 2023 reporting period/CY 2025 payment determination.

[275] We note that, if finalized, an OP/measure number will be assigned for this measure in the final rule.

4. 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 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

a. Background

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.

b. Proposed Form, Manner, and Timing for OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

As discussed in section XV.B.5.a. of this proposed rule, we are proposing to begin data collection of five survey-based measures derived from the OAS CAHPS Survey beginning with voluntary data collection and reporting for the CY 2023 reporting period/CY 2025 payment determination,[276] followed by mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. The OAS CAHPS survey contains three OAS CAHPS composite survey-based measures and two global survey-based measures. In this section, we are proposing requirements related to survey administration, vendors, and oversight activities.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794), we previously discussed the form, manner, and timing of this survey. In this proposed rule, we are reaffirming our approach to the form, manner, and timing which OAS CAHPS information will be submitted and we are now proposing to add two additional data collection modes (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents),[277] beginning with voluntary data collection for the CY 2023 reporting period/CY 2025 payment determination and continuing for mandatory reporting for subsequent years. For more information about the modes of administration, we refer readers to the OAS CAHPS website: *https://oascahps.org*. We reiterate our clarification from when we adopted these measures in the CY 2017 OPPS/ASC final rule with comment period that, when implemented, hospital outpatient departments that anticipate receiving more than 300 surveys would be required to either: (1) Randomly sample their eligible patient population; or (2) survey their entire OAS CAHPS eligible patient population (81 FR 79773). We also refer readers to section XVI.D.1.d. of the preamble of this proposed rule where we are proposing similar policies for the ASCQR Program.

(1) Survey Requirements

The data collection modes as currently specified for the survey include three administration modes: (1) Mail-only; (2) telephone-only; and (3) mixed mode (mail with telephone follow-up of non-respondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*) for materials for each mode of survey administration. In the 2018 OPPS/ASC final rule with comment period, we expressed interest in investigating the feasibility of offering the OAS CAHPS Survey using a web-based format (82 FR 59433). As a result, we designed a mode experiment to assess the impact of adding web-based survey administration. This mode experiment tested five administration modes with patients who receive outpatient surgical care: (1) Mail-only; (2) telephone-only; (3) web-only; (4) web with mail follow-up; and (5) web with a telephone follow-up. Data collection was completed in the fall of 2019. Response rates by mode in the experiment were: 35 percent (mail-only); 19 percent (telephone-only); 29 percent (web-only); 39 percent (web with mail follow-up); and 35 percent (web with telephone follow-up).

Based on these results, in addition to the three previously established modes, in this proposed rule we are proposing to incorporate two more administration methods: (1) Mixed mode web with mail follow-up of non-respondents, and (2) mixed mode web with telephone follow-up of non-respondents. This would allow a total of five methods of survey administration for reporting beginning with voluntary data collection and reporting as part of the Hospital OQR Program for the CY 2023 reporting period/CY 2025 payment determination[278] and mandatory reporting for the CY 2024 reporting period/CY 2026 payment determination—the first year the survey would be required if our proposal in section XV.B.5.a. is finalized as proposed. We are not proposing a purely web-based format at this time because the use of a web-based mode is included in the two mixed modes options being proposed and the purely web-based format would create response bias since not all patients have the ability to respond by web.

For all five proposed modes of administration as part of the Hospital OQR Program, we are proposing that data collection must be initiated no later than 21 calendar days after the month in which a patient has a surgery or procedure at a hospital and completed within 6 weeks (42 days) after initial contact of eligible patient begins, beginning with voluntary reporting in the CY 2023 reporting period/CY 2025 payment determination and subsequent years. Under this proposal, hospitals, via their CMS-approved vendors (discussed in section XV.D.4.b.(2) of this proposed rule.), must make multiple attempts to contact eligible patients unless the patient refuses or the vendor learns that the patient is ineligible to participate in the survey. In addition, we are proposing that hospitals, via their CMS-approved survey vendor, collect survey data for eligible patients using the established quarterly deadlines to report data to CMS for each data collection period unless the hospital has been exempted from the OAS CAHPS Survey requirements under the low volume exemption. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79774) where we previously established the low volume exemption, which

[276] As stated in section XV.B.5.a., we note that National OAS CAHPS voluntary reporting program is independent of the Hospital OQR Program, but the submission process will otherwise remain unchanged. This proposal is intended to clarify that voluntary reporting of OAS CAHPS would begin as part of the Hospital OQR Program in the CY 2023 reporting period until mandatory reporting would begin in the CY 2024 reporting period/CY 2026 payment determination and for subsequent years, if both proposals are finalized.

[277] The two additional modes will be available as part of National OAS CAHPS voluntary reporting program in 2022.

[278] As stated in section XV.B.5.a., we note that the two modes (web with mail follow-up of non-respondents; and web with telephone follow-up of non-respondents) will be available beginning in CY 2022 for National OAS CAHPS voluntary reporting, and then if finalized, available as part of OQR Program's reporting beginning in the CY 2023 reporting period and subsequent years.

exempts hospital outpatient departments with fewer than 60 survey-eligible patients during the ''eligibility period,'' (which is the calendar year before the data collection period), that submit the participation exemption request form, which would be made available on the OAS CAHPS Survey website (*https://oascahps.org*) on or before May 15 of the data collection year. As finalized previously, all exemption requests would be reviewed and evaluated by CMS (81 FR 79774). For hospitals that do not have an exemption, the submission deadlines would be posted on the OAS CAHPS Survey website (*https://oascahps.org*). Late submissions would not be accepted.

As discussed in more detail in this section of the proposed rule, compliance with the OAS CAHPS Survey protocols and guidelines, including this monthly data collection requirement as part of each quarterly data submission, would be overseen by CMS or its contractor who would receive approved vendors' monthly submissions, review the data, and analyze the results. We previously finalized (81 FR 79774) all data collection and submission for the OAS CAHPS Survey measures would be reported at the Medicare participating hospital level, as identified by its CCN. If data collection and reporting becomes mandatory beginning with the CY 2024 reporting period as proposed, under this proposal, all locations that offer outpatient services, of each eligible Medicare participating hospital, would be required to participate in the OAS CAHPS Survey (81 FR 79793), except for those that meet and receive an exception for having fewer than 60 survey-eligible patients during the year preceding the data collection period (81 FR 79773). Therefore, the survey data reported using a Medicare participating hospital's CCN must include all eligible patients from all outpatient locations (whether the hospital outpatient department is on campus or off campus) of an eligible Medicare participating hospital; or if more than 300 completed surveys are anticipated, a hospital can choose to randomly sample their eligible patient population (81 FR 79784).

In this proposed rule, we also propose that survey vendors acting on behalf of hospitals must submit data by the specified data submission deadlines, which generally would be posted on the OAS CAHPS Survey website located at *https://oascahps.org/Data-Submission/Data-Submission-Deadlines*. If a hospital's data are submitted after the data submission deadline, it would not fulfill the OAS CAHPS quality reporting requirements. Therefore, in regard to any OAS CAHPS reporting, we would strongly encourage hospitals to be fully apprised of the methods and actions of their survey vendors—especially the vendors' full compliance with OAS CAHPS Survey administration protocols—and to carefully inspect all data warehouse reports in a timely manner.

We reiterate that the use of predictive or auto dialers in telephonic survey administration is governed by the Telephone Consumer Protection Act (TCPA) (47 U.S.C. 227) and subsequent regulations promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and Federal Trade Commission. We refer readers to the FCC's declaratory ruling released on July 10, 2015 further clarifying the definition of an auto dialer, available at: *https://apps.fcc.gov/edocs_public/attachmatch/FCC-15-72A1.pdf*. In the telephone-only and mixed mode survey administration methods involving telephone, hospitals and vendors must comply with the regulations and any other applicable regulations. To the extent that any existing CMS technical guidance conflicts with the TCPA or its implementing regulations regarding the use of predictive or auto dialers, or any other applicable law, CMS would expect vendors to comply with applicable law.

We invite comments on our proposals as discussed previously.

(2) Vendor Requirements

We are not proposing new vendor requirements, but reiterate the vendor requirements finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793 through 79794) to ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient care, and is not influenced by the hospital. We finalized that hospitals must contract with a CMS-approved OAS CAHPS Survey vendor to conduct or administer the survey. We believe that a neutral third-party should administer the survey for hospitals, and it is our belief that an experienced survey vendor would be best able to ensure reliable results. CAHPS Survey-approved vendors are also already used or required in the following CMS quality programs: The Hospital IQR Program (71 FR 68203 through 68204); the Hospital VBP Program (76 FR 26497, 26502 through 26503, and 26510); the End Stage Renal Disease Quality Improvement Program (76 FR 70269 through 70270); the Home Health QRP (80 FR 68709 through 68710); and the Hospice QRP (80 FR 47141 through 47207).

Information about the list of approved survey vendors and how to authorize a vendor to collect data on a hospital's behalf is available through the OAS CAHPS Survey website at: *https://oascahps.org*. The web portal has both public and secure (restricted access) sections to ensure the security and privacy of selected interactions. As mentioned previously, requirements for survey vendors were previously finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793 through 79794) and codified at § 419.46(h)(2). Hospitals will need to register on the OAS CAHPS Survey website (*https://oascahps.org*) in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each hospital must then administer (via its vendor) the survey to all eligible patients (or for those anticipating more than 300 completed surveys, randomly sample their eligible patient population) treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website.

5. Data Submission Requirements for Measures Submitted via a Web-Based Tool for the CY 2023 Payment Determination and Subsequent Years

a. Data Submission Requirements for Measures Submitted via a CMS Web-Based Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521), and the QualityNet website available at: *https://qualitynet.cms.gov* for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. We are not proposing any changes to these policies.

The following previously adopted quality measures require data to be submitted via a CMS web-based tool for the CY 2022 reporting period/CY 2024 payment determination and subsequent years:

- OP–22: Left Without Being Seen (NQF #0499); and
- OP–29: Endoscopy/Polyp Surveillance: Appropriate Follow-up

Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658).

(1) Proposed Form, Manner, and Timing for Reporting OP–31: Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536)

The following measure that is being proposed for modification in this proposed rule would require data to be submitted via a CMS web-based tool for the CY 2023 reporting period/CY 2025 payment determination and subsequent years:

- OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

We propose that this measure would be submitted according to our existing policies for data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal). As noted earlier, we are not proposing changes to those policies. We invite public comment on our proposal.

b. Data Submission Requirements for Measures Submitted via the CDC NHSN Website

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the CDC NHSN website. While we are not proposing any changes to those policies in this proposed rule, we are proposing policies specific to the proposed COVID–19 Vaccination Coverage Among HCP measure, which would be submitted via the CDC NHSN website.

(1) Proposed Form, Manner, and Timing for the COVID–19 Vaccination Coverage Among HCP Measure Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination and Subsequent Years

For the COVID–19 Vaccination Coverage Among HCP measure, we are proposing to require reporting data on the number of HCP who have received the completed vaccination course of a COVID–19 vaccine by each individual facility's CCN.

For the COVID–19 Vaccination Coverage Among HCP measure, we are proposing that facilities would report COVID–19 vaccination data to the NHSN for at least one week each month, beginning with the January 1, 2022 through December 31, 2022 reporting period affecting the CY 2024 payment determination and continuing with quarterly reporting deadlines for subsequent years. If facilities report more than one week of data in a month, the most recent week's data would be used for measure calculation purposes. We propose that hospitals would report the measure through the NHSN web-based surveillance system.[279] Specifically, hospitals would use the COVID–19 vaccination data reporting modules in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible to have worked at the facility that week (denominator) and the number of those HCP who have received COVID–19 vaccination (numerator). Specific details on data submission for this measure can be found in the CDC's Overview of the Healthcare Safety Component, available at *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf*. We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75097 through 75100) for details about requirements for measure data submitted via the NHSN. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the reporting periods for the quarter in four-quarter increments, when four quarters of data are available.

With respect to public reporting of this measure, for each CCN, a percentage of the HCP who received a complete course of the COVID–19 vaccine would be calculated and publicly reported on the *Care Compare* website, so that the public would know what percentage of the HCP have been vaccinated in each hospital. Once four quarters are available, data would be refreshed on a quarterly basis with the most recent four quarters. This quarterly average COVID–19 vaccination coverage would be publicly reported. We invite public comment on our proposals.

6. Proposed eCQM Reporting and Submission Requirements

a. Background

We believe that collection and reporting of data through health information technology would greatly simplify and streamline reporting for many CMS quality reporting programs. Through electronic reporting, hospitals will be able to leverage EHRs to capture, calculate, and electronically submit quality data to CMS for the Hospital OQR Program.

We believe that automated electronic extraction and reporting of clinical quality data would significantly reduce the administrative burden on hospitals for the Hospital OQR Program. We believe that the use of CEHRT can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of eCQMs. In previous rules, we stated our intent and assessment of the inclusion of eCQMs into the Hospital OQR Program, and we have sought public comment on the addition of such measures into the measure set. We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75106 through 75107), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66956 through 66961), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70516 through 70518), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79785 through 79790), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59435 through 59438) for more details on previous discussion regarding future measure concepts related to eCQMs and electronic reporting of data for the Hospital OQR Program, including stakeholder support for the introduction of eCQMs into the Program. Measure stewards and developers have worked to advance eCQMs that would be reported in the outpatient setting and we believe the introduction of eCQMs in the Hospital OQR Program is timely. We also believe this is important in aligning the Hospital OQR Program with the Medicare Promoting Interoperability Program and the Hospital IQR Program.

b. Proposed eCQM Reporting and Data Submission Requirements Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

In section XV.B.4.c. of the preamble of this proposed rule, we discuss the proposed adoption of the STEMI eCQM. In this proposed rule, we are proposing a progressive increase in the number of quarters for which hospitals report eCQM data. Increasing the number of reported quarters to be reported has several benefits. Primarily, a single quarter of data is not enough to capture trends in performance over time. Evaluating multiple quarters of data would provide a more reliable and accurate picture of overall performance. Further, reporting multiple quarters of data would provide hospitals with a more continuous information stream to monitor their levels of performance. Ongoing, timely data analysis can better identify a change in performance that may necessitate investigation and potentially corrective action.

However, we believe that starting with limited voluntary reporting would

[279] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

give hospitals more time to gain experience with reporting data (including time to implement the eCQM and provide training to support eCQM reporting, if necessary). Similar to what was established for the Hospital IQR Program (82 FR 38355), we believe that increasing the number of quarters for which hospitals report eCQM data would produce more comprehensive and reliable quality measure data for patients and providers. In section XV.B.4.c. of this proposed rule, we are proposing to adopt the STEMI eCQM with voluntary reporting beginning with the CY 2023 reporting period. For the CY 2023 reporting period, we propose that hospitals that submit STEMI eCQM data during this reporting period voluntarily submit any quarter(s) of data. Hospitals that chose to submit voluntarily must submit in compliance with the eCQM certification requirements proposed in sections XV.D.6.c., XV.D.6.d, and XV.D.6.e. of this proposed rule.

For the CY 2024 reporting period/CY 2026 payment determination, we propose that hospitals report one self-selected calendar quarter of data for the STEMI eCQM. We note that in section XV.B.4.c. of this proposed rule, we are proposing that the STEMI eCQM is required beginning with the CY 2024 reporting period/CY 2026 payment determination.

For the CY 2025 reporting period/CY 2027 payment determination, we propose to increase the amount of data required. We are proposing that hospitals report two self-selected calendar quarters of data for the required STEMI eCQM.

For the CY 2026 reporting period/CY 2028 payment determination, we propose to further increase the amount of data required for the STEMI eCQM. Specifically, in this proposed rule, we are proposing to require that hospitals report three self-selected calendar quarters of data for the CY 2026 reporting period/CY 2028 payment determination for the required STEMI eCQM. Beginning with the CY 2027 reporting period/CY 2029 payment determination, we propose to require that hospitals report all four calendar quarters (one calendar year) of data for the required STEMI eCQM.

We also refer readers to Table 51 for a summary of the proposed quarterly data increase in eCQM reporting beginning with the CY 2023 reporting period.

TABLE 51: Proposed Progressive Increase in eCQM Reporting Beginning with the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

Calendar Year Period	Calendar Quarters of Reporting	Reporting
CY 2023 Reporting Period/CY 2025 Payment Determination	Any quarter(s)	Voluntary
CY 2024 Reporting Period/CY 2026 Payment Determination	One self-selected quarter	Mandatory
CY 2025 Reporting Period/CY 2027 Payment Determination	Two self-selected quarters	Mandatory
CY 2026 Reporting Period/CY 2028 Payment Determination	Three self-selected quarters	Mandatory
CY 2027 Reporting Period/CY 2029 Payment Determination and Subsequent Years	Four quarters (one calendar year)	Mandatory

We invite public comment on our proposals.

c. Proposed Electronic Quality Measure Certification Requirements for eCQM Reporting

(1) Proposal To Require Use of 2015 Edition Cures Update Certified Technology Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

In May 2020, the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) finalized updates to the 2015 Edition of health IT certification criteria (hereto referred to as the ''2015 Edition Cures Update''). These updates included revisions to the clinical quality measurement certification criterion at 45 CFR 170.315(c)(3) to refer to CMS Quality Reporting Data Architecture (QRDA) IGs and remove the Health Level 7 (HL7®) QRDA standard from the relevant health IT certification criteria (85 FR 25645). The ONC 21st Century Cures Act final rule provided health IT developers up to 24 months from May 1, 2020 to make technology certified to the updated and/or new criteria available to their customers (85 FR 25670). In November 2020, ONC issued an interim final rule with comment (85 FR 70064) which extended the compliance deadline for the update to the Clinical Quality Measures-Report criterion until December 31, 2022 (85 FR 70075). These updates were finalized to reduce burden on health IT developers under the ONC Health IT certification program (85 FR 25686) and have no impact on providers' existing reporting practices for CMS programs.

For the Hospital OQR Program, we propose to require hospitals to utilize certified technology updated consistent with the 2015 Edition Cures Update for the CY 2023 reporting period/CY 2025 payment determination and subsequent years, which includes both the voluntary period and required submissions. We note that this proposal is in alignment with the Hospital IQR Program proposal in the FY 2022 IPPS/LTCH PPS proposed rule that requires use of technology updated consistent with 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination (86 FR 25595). We invite public comment on our proposal.

d. File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

(1) File Format for EHR Data

Data can be collected in EHRs and health information technology systems using standardized formats to promote consistent representation and interpretation, as well as to allow for systems to compute data without needing human interpretation. As described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701), these standards are referred to as content exchange standards because the standard details how data should be represented and the relationships between data elements. This allows the data to be exchanged across EHRs and health IT systems while retaining their meaning. Commonly used content exchange standards include the QRDA. The QRDA standard provides a document format and standard structure to electronically report quality measure data. We believe electronically reporting data elements formatted according to the QRDA standard would promote consistent representation and more efficient calculation of eCQM measure results.

Therefore, in alignment with the Hospital IQR Program file format requirements (85 FR 58940), we are proposing the requirements beginning with the CY 2023 reporting period/CY 2025 payment determination. Specifically, we are proposing that hospitals: (1) Must submit eCQM data via the QRDA Category I (QRDA I) file format; [280] (2) may use third parties to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. Hospitals could meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemptions. We discuss the zero denominator declaration and case threshold exemptions in the subsequent sections. We also refer readers to section XV.B.8. where we outline the maintenance of technical specifications including those for eCQMs.

Under this proposal, we expect QRDA I files to reflect data for one patient per file per quarter with five key elements necessary to identify the file:

- CMS Certification Number (CCN);
- CMS Program Name;
- EHR Patient ID;
- Reporting period specified in the Reporting Parameters Section; and
- EHR Submitter ID.

We invite public comment on our proposal.

(2) Zero Denominator Declarations

We understand there may be situations in which a hospital does not have data to report on a particular eCQM. Therefore, we propose if the hospital's EHR is certified to an eCQM, but the hospital does not have patients that meet the denominator criteria of that eCQM, the hospital can submit a zero in the denominator for that eCQM. Submission of a zero in the denominator for an eCQM counts as a successful submission for that eCQM for the Hospital OQR Program. For example, if the hospital within the previously mentioned health system does not provide fibrinolytic therapy, but one of the eCQMs the health system's EHR is certified to is a fibrinolytic therapy measure, that hospital's EHR may render a zero in the denominator for that eCQM. The hospital would therefore report a zero denominator for that fibrinolytic therapy eCQM, and this would count toward the required eCQMs for the Hospital OQR Program. Hospitals within that health system for which that fibrinolytic therapy eCQM does apply would provide data on that measure. We invite public comment on our proposal.

(3) Case Threshold Exemptions

We understand that in some cases, a hospital may not meet the case threshold of discharges for a particular eCQM. We propose to align with the case threshold exemption from the Medicare Promoting Interoperability Program (77 FR 54080) and the Hospital IQR Program (79 FR 50324). As stated for the Hospital IQR Program, the case threshold exemption means that for each quality measure for which hospitals do not have a minimum number of patients that meet the patient population denominator criteria for the relevant reporting period, hospitals would have the ability to declare a ''case threshold exemption'' if they have five or fewer applicable discharges. Specifically, for the Hospital OQR Program we propose that beginning with the CY 2023 reporting period/CY 2025 payment determination, if a hospital's EHR system is certified to report an eCQM and the hospital experiences 5 or fewer outpatient discharges per quarter or 20 or fewer outpatient discharges per year (Medicare and non-Medicare combined), as defined by an electronic clinical quality measure's denominator population, that hospital could be exempt from reporting on that electronic clinical quality measure. Case threshold exemptions are entered on the Denominator Declaration screen within the HQR System (formerly referred to as the QualityNet Secure Portal) available during the submission period.[281] The exemption would not have to be used; hospitals could report those individual cases if they would like to. We invite public comment on our proposal.

e. Submission Deadlines for eCQM Data

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), the Hospital IQR Program aligned their eCQM submission deadline with that of the Medicare Promoting Interoperability Program. The eCQM submission deadline for those two programs is the end of two months following the close of the CY (beginning with the CY 2017 reporting period/FY 2019 payment determination and for subsequent years).

In this proposed rule, for the Hospital OQR Program, we are also proposing to require eCQM data submission by the end of 2 months following the close of the calendar year for the CY 2023 reporting period/CY 2025 payment determination and for subsequent years. We believe that by aligning with the Hospital IQR and Promoting Interoperability Programs' deadlines, we would not add unnecessary burden. For example, for the CY 2023 reporting period/CY 2025 payment determination, hospitals that choose to voluntarily report that calendar year would be required to submit eCQM data by February 29, 2024, which is the end of 2 months following the close of the calendar year (December 31, 2023).

In crafting this proposal, we also considered proposing a submission deadline of May 15 to align with the submission deadline for Hospital OQR web-based measures. Under the Hospital OQR Program, the data submission period for web-based measures (for example, OP–29 and OP–31) extends through May 15 (we note the submission deadline may be moved to the next business day if it falls on a weekend or Federal holiday). However, we ultimately proposed instead to align eCQM data submission deadlines across quality reporting programs, because we believe that it would be less burdensome for hospitals.

We invite public comment on our proposal.

7. Population and Sampling Data Requirements for the CY 2022 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. We are not proposing any changes to these policies in this proposed rule. We note that we are not proposing any population and sampling data policies related to eCQM reporting, because we would expect data for all patients who meet the patient population denominator criteria to be reported, if our eCQM-related proposals are finalized as proposed.

8. Review and Corrections Period for Measure Data Submitted to the Hospital OQR Program

a. Chart-Abstracted Measures

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 and 67014) where

[280] QRDA I is an individual patient-level quality report that contains quality data for one patient for one or more eCQMs. QRDA creates a standard method to report quality measure results in a structured, consistent format and can be used to exchange eCQM data between systems. For further detail on QRDA I, the most recently available QRDA I specifications and Implementation Guides (IGs) can be found at: *https://ecqi.healthit.gov/qrda.*

[281] CMS Adds New Features to Denominator Declaration Screen for eCQM Reporting, available at: *https://qualitynet.cms.gov/news/5fa161829314190021d3c262.*

we formalized a review and corrections period for chart-abstracted measures in the Hospital OQR Program. We are not proposing any changes to these policies in this proposed rule.

b. Web-Based Measures

In the CY 2021 OPPS/ASC final rule (85 FR 86184), we finalized and codified to expand our review and corrections policy to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

c. Electronic Clinical Quality Measures (eCQMs)

In this proposed rule, we are proposing that hospitals would have a review and corrections period for eCQM data submitted to the Hospital OQR Program. We propose a review and corrections period for eCQM data which would run concurrently with the data submission period. The review and corrections period is from the time the submission period opens to the submission deadline. In the HQR System (formerly referred to as the QualityNet Secure Portal), providers can submit QRDA Category I test and production data files and can correct QRDA Category I test and production data files before production data is submitted for final reporting. We encourage early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting. The HQR System does not allow data to be submitted or corrected after the annual deadline. We refer readers to the HQR System website (available at: *https://hqr.cms.gov/hqrng/login*) and the eCQI Resource Center (available at: *https://ecqi.healthit.gov/*) for more resources on eCQM reporting.

We invite public comment on our proposal.

d. OAS CAHPS Measures

Each hospital administers (via its vendor) the survey for all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website as stated in section XV.D.4.b.(2). of this proposed rule. As finalized in the CY 2017 OPPS/ASC final rule with comment period, data cannot be altered after the data submission deadline but can be reviewed prior to the submission deadline (81 FR 79793).

9. Hospital OQR Program Validation Requirements

a. Background

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 through 72106), 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), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), and 42 CFR 419.46(f) for our policies regarding validation.

b. Proposal To Use Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination and Subsequent Years

Currently, hospitals may choose to submit paper copies of medical records for chart-abstracted measure validation, or they may submit copies of medical records for validation by securely transmitting electronic versions of medical information (79 FR 66965 through 66966). Submission of electronic versions can either entail downloading or copying the digital image of the medical record onto Compact Disc (CD), Digital Video Disc (DVD), or flash drive, or submission of Portable Document Format (PDF) using a secure file transmission process after logging into the HQR System (formerly referred to as the QualityNet Secure Portal) (79 FR 66966). We reimburse hospitals at $3.00 per chart (FY 2016 IPPS/LTCH PPS final rule (80 FR 49763)).

We strive to provide the public with accurate quality data while maintaining alignment with hospital recordkeeping practices. We appreciate that hospitals have rapidly adopted EHR systems as their primary source of information about patient care, which can facilitate the process of producing electronic copies of medical records. Additionally, we monitor the medical records submissions to the CMS Clinical Data Abstraction Center (CDAC) contractor and have found that almost two-thirds of hospitals already use the option to submit PDF copies of medical records as electronic files. In our assessment based on this monitoring, we believe requiring electronic file submissions can be a more effective and efficient process for hospitals selected for validation.

Therefore, in this proposed rule, we are proposing to discontinue the option for hospitals to send paper copies of, or CDs, DVDs, or flash drives containing medical records for validation affecting the CY 2024 payment determination (that is, beginning with data submission for Q1 of CY 2022). We are proposing to require hospitals to instead submit only electronic files when submitting copies of medical records for validation of chart-abstracted measures, beginning with validation affecting the CY 2024 payment determination (that is, Q1 of CY 2022) and for subsequent years. Under this proposal, hospitals would be required to submit PDF copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process as directed by CDAC. We would continue to reimburse hospitals at $3.00 per chart, consistent with the current reimbursement amount for electronic submissions of charts. We note that this process would align with that for the Hospital IQR Program (FY 2016 IPPS/LTCH PPS final rule (85 FR 58949)).

Requiring electronic file submissions reduces the burden of not only coordinating numerous paper-based pages of medical records, but also of having to then ship the papers or physical digital media storage to the CDAC. Therefore, we believe it is appropriate to require that hospitals use electronic file submissions via a CMS-approved secure file transmission process. We invite public comment on our proposal.

c. Proposal To Change the Time Period for Chart-Abstracted Measure Data Validation for Validations Affecting the CY 2024 Payment Determination and Subsequent Years

We refer readers to the chart-abstracted validation requirements and methods we adopted in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75117 through 75118) and codified at 42 CFR 419.46(f)(1) for the CY 2024 payment determination and subsequent years. In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 calendar days from the date of the request to submit the requested records. If any record(s) were not received by the 45-day requirement, the CMS CDAC contractor assigned a ''zero'' validation score to each measure in a missing record. Using data from the CDAC, we have found that a large majority of hospitals that have participated in Hospital OQR Program data validation efforts have submitted their records prior to 30 calendar days in the current process. Furthermore,

outpatient records typically contain significantly fewer pages than the inpatient records that hospitals have been submitting to the Hospital IQR Program for several years, which suggests that outpatient records could be gathered in less time and use less resources.

Therefore, in this proposed rule, we are proposing to revise § 419.46(f)(1) to change the time period given to hospitals to submit medical records to the CDAC contractor from 45 calendar days to 30 calendar days, beginning with medical record submissions for encounters in Q1 of CY 2022/ validations affecting the CY 2024 payment determination and for subsequent years. We are proposing this deadline modification to reduce the time needed to complete validation, provide hospitals with feedback on their abstraction accuracy in a timelier manner, and to further align with the Hospital IQR Program's validation policy (76 FR 51645). We invite public comment on our proposal.

d. Targeting Criteria

(1) Background

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), we finalized a validation selection process in which we select a random sample of 450 hospitals for validation purposes and select an additional 50 hospitals based on specific criteria. We finalized a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68485 through 68486), that for the CY 2014 payment determination and subsequent years, a hospital will be preliminarily selected for validation based on targeting criteria if it fails the validation requirement that applies to the previous year's payment determination. We also refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68486 through 68487) for a discussion of finalized policies regarding our medical record validation procedure requirements. We codified at § 419.46(f)(3) that we select a random sample of 450 hospitals for validation purposes, and select an additional 50 hospitals for validation purposes based on the following criteria:

- The hospital fails the validation requirement that applies to the previous year's payment determination; or
- The hospital has an outlier value for a measure based on the data it submits. An ''outlier value'' is 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.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441), we clarified that an ''outlier value'' for purposes of this targeting is defined as a measure value that appears to deviate markedly from the measure values for other hospitals.

(2) Proposal To Add Targeting Criteria

Beginning with validations affecting the CY 2022 reporting period/CY 2024 payment determination and subsequent years, we are proposing to add to the two established targeting criteria used to select the 50 additional hospitals. Specifically, we are proposing to revise § 419.46(f)(3) to add the following criteria for targeting the additional 50 hospitals:

- Any hospital that has not been randomly selected for validation in any of the previous 3 years.
- Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.

We believe these proposals would allow more hospitals the opportunity for validation. First, by adding targeting criteria for any hospital that has not been randomly selected for validation in any of the previous 3 years, we can ensure that hospitals are eligible to be validated on a regular basis even if they are not selected under the randomly selected sample. Second, the option to selectively review hospitals that have a confidence interval that includes 75 percent is important because hospitals whose confidence interval includes 75 percent indicates a higher level of uncertainty as to the reliability of data for that particular hospital. By adding the targeting criteria for hospitals with two-tailed confidence interval that includes 75 percent, we can target those hospitals that are in the statistical margin of error for their accuracy (which includes hospitals that both pass and fail on this level). These proposals also align Hospital OQR Program validation with additional aspects of Hospital IQR Program validation (77 FR 53553). We believe that these proposed additional criteria would improve data quality by increased targeting of hospitals with possible or confirmed past data quality issues. Additionally, this proposal would respond to concerns that CMS does not have a methodology to address hospitals for which both passing and falling levels of accuracy were included for the statistical margin of error.[282] We invite public comment on our proposals.

[282] Government Accountability Office. ''Hospital Quality Data. CMS needs more rigorous methods to ensure reliability of publicly released data''. GAO–06–54, January 2006.

e. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443) and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86185), where we finalized and codified a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction.

We are not proposing any changes to these policies in this proposed rule.

10. Extraordinary Circumstances Exception (ECE) Process for the CY 2022 Payment Determination and Subsequent Years

a. Background

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(e) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program.

b. Proposal To Expand the Extraordinary Circumstances Exemption to eCQMs

As part of our proposed policies in support of the introduction of eCQMs into the Hospital OQR Program, beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years, we are proposing to expand our established Extraordinary Circumstances Exceptions policy to allow hospitals to request an exception from the Hospital OQR Program's eCQM reporting requirements based on hardships preventing hospitals from electronically reporting. We note that our proposal aligns with the Hospital IQR Program's Extraordinary Circumstances Exceptions policy for eCQMs (80 FR 49695, 42 CFR 412.140(c)(2)).

Under this proposal, applicable hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as

vendor issues outside of the hospital's control (including a vendor product losing certification). In addition, under the Hospital OQR Program, we may consider being a newly participating hospital as undergoing hardship such that newly participating hospitals can apply for an exemption for the applicable program year. Newly participating hospitals are required to begin data submission under the Hospital OQR Program procedural requirements at § 419.46(d)(1), which describes submission and validation of Hospital OQR Program data.

We also propose that a hospital participating in the Hospital OQR Program that wishes to request an exception must submit its request to CMS by April 1 following the end of the reporting calendar year in which the extraordinary circumstances occurred. For example, if an extraordinary circumstance occurred on or by December 31, 2024, the ECE request must be submitted by April 1, 2025. Specific requirements for submission of a request for an exception would be available on the QualityNet website available at: *https://qualitynet.cms.gov/*.

We invite public comment on our proposals.

11. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2022 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), the CY 2021 OPPS/ASC final rule with comment period (85 FR 68185), and 42 CFR 419.46(g) for our reconsideration and appeals procedures. We are not proposing any changes to these policies in this proposed rule.

E. Proposed Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2022 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 the proposed rule, 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).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor − 0.02)

Reporting Ratio = Reduced Conversion Factor/Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor − 0.02)/(1 + OPD update factor)

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 proposed rule.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2022

We propose 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 2022 annual payment update factor. For this CY 2022 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which when multiplied by the proposed full conversion factor of $84.457 equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $82.810. We propose to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We propose to continue 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 propose to continue to exclude services paid under New Technology APCs. We propose 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 propose 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 propose 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. In addition to our proposal to implement the policy through the use of a reporting ratio, we also propose to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2022, the proposed reporting ratio is 0.9805, which when multiplied by the final full conversion factor of 84.457 equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of 82.810.

XVI. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIV.A.1. of the CY 2020 OPPS/ASC final rule with comment period (84 FR 61410) for a general overview of our quality reporting programs and to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) where we previously discussed our Meaningful Measures Framework.

2. Statutory History of the ASCQR Program

We refer readers to 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 refer readers to the CY 2014 through 2021 OPPS/ASC final rules with comment period for an overview of the regulatory history of the ASCQR Program:

- CY 2014 OPPS/ASC final rule (78 FR 75122);
- CY 2015 OPPS/ASC final rule (79 FR 66966 through 66987);
- CY 2016 OPPS/ASC final rule (80 FR 70526 through 70538);
- CY 2017 OPPS/ASC final rule (81 FR 79797 through 79826);
- CY 2018 OPPS/ASC final rule (82 FR 59445 through 59476);
- CY 2019 OPPS/ASC final rule (83 FR 59110 through 59139);
- CY 2020 OPPS/ASC final rule (84 FR 61420 through 61434); and
- CY 2021 OPPS/ASC final rule (85 FR 86187 through 86193).

We have codified requirements under the ASCQR Program at 42 CFR, part 16, subpart H (42 CFR 416.300 through 416.330).

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 the ASCQR Program quality measure selection. We are not proposing any changes to these policies in this proposed rule.

2. Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously finalized 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 such measures 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). We are not proposing any changes to this policy in this proposed rule.

b. Removal Factors for ASCQR Program Measures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115), we clarified, finalized, and codified at § 416.320 an updated set of factors [283] and the process for removing measures from the ASCQR Program. We are not proposing any changes to the measure removal factors in this proposed rule.

3. Proposal To Adopt a New Measure for the ASCQR Program Measure Set

In this proposed rule, we are proposing to adopt one new measure: COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with the CY 2022 reporting period/2024 payment determination.

a. Proposal To Adopt the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination

(1) Background

On January 31, 2020, the Secretary declared a public health emergency (PHE) for the United States (U.S.) in response to the global outbreak of SARS–CoV–2, a novel coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[284] COVID–19 is a contagious respiratory infection [285] that can cause serious illness and death. Older individuals, some racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[286] [287] As of July 2, 2021, the U.S. has reported over 33 million cases of COVID–19 and over 600,000 COVID–19 deaths.[288] Hospitals and health systems significant surges of COVID–19 patients as community infection levels increased.[289] From December 2, 2020 through January 30, 2021, more than 100,000 Americans with COVID–19 were hospitalized at the same time.[290]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[291] Ongoing research indicates that fully vaccinated people without immunocompromising conditions are able to engage in most activities with very low risk of acquiring or transmitting SARS–CoV–2, and the Centers for Disease Control and Prevention (CDC) issued new guidance for fully vaccinated individuals on May 28, 2021.[292] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[293] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[294] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface [295] and that in certain circumstances, infection can occur through airborne transmission.[296] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed COVID–19 infection, regardless of whether the individual has symptoms.[297] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between HCP and patients or from patient to patient given the close contact that may occur during the provision of care.[298] The CDC has emphasized that health care settings can be high-risk places for COVID–19 exposure and transmission.[299]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[300] On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[301] Subsequently, the FDA issued EUAs for additional COVID–19 vaccines.[302] [303]

As part of its national strategy to address COVID–19, the White House stated on March 25, 2021 that it would work with states and the private sector to execute an aggressive vaccination strategy and outlined a goal of

[283] We note that we previously referred to these factors as ''criteria'' (for example, 79 FR 66967 through 66969); we now use the term ''factors'' to align the ASCQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

[284] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[285] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[286] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[287] Centers for Disease Control and Prevention. (2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html*.

[288] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

[289] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895*. Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html*.

[290] US Currently Hospitalized | The COVID Tracking Project. Accessed January 31, 2021 at: *https://covidtracking.com/data/charts/us-currently-hospitalized*.

[291] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[292] Centers for Disease Control and Prevention. (2021). Interim Public Health Recommendations for Fully Vaccinated People. Accessed on June 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html*.

[293] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[294] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[295] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[296] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html*.

[297] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html*.

[298] Centers for Disease Control and Prevention. (2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission*.

[299] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[300] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[301] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download*.

[302] U.S. Food and Drug Administration. (2021). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download*.

[303] U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download*.

administering 200 million shots in 100 days[304] On April 21, 2021, it was announced that this goal had been achieved.[305] Although the goal of the U.S. Government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, the Department of Health and Human Services, the Department of Defense, and the CDC, recommended that early vaccination efforts focus on those critical to the PHE response, including HCP, and individuals at highest risk for developing severe illness from COVID–19.[306] The CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity.[307] Reportedly most states followed this recommendation,[308] and HCP began receiving the vaccine in mid-December of 2020.[309]

Frontline healthcare workers, such as those employed in ASCs, have been prioritized for vaccination in most locations. There are approximately 18 million healthcare workers in the U.S.[310] A survey of HCP found that 66 percent of hospital HCP and 64 percent of outpatient clinic HCP reported receiving at least one dose of the vaccine.[311] As of July 2, 2021, the CDC reported that over 328 million doses of COVID–19 vaccine had been administered and approximately 155.9 million people had received full doses.[312] The White House indicated on April 6, 2021 that the U.S. retains sufficient vaccine supply, and every adult became eligible to receive the vaccine beginning April 19, 2021.[313]

We believe it is important to require that ASCs report HCP vaccination information for health care facilities to assess whether these facilities are taking steps to limit the spread of COVID–19 among their health care workers and to help sustain the ability of ASCs to continue serving their communities throughout the PHE and beyond. Therefore, we are proposing to adopt a new measure, COVID–19 Vaccination Coverage Among HCP, beginning with the CY 2024 payment determination. For that payment year, ASCs would be required to report data quarterly on the measure for the January 2022 through December 2022 reporting period. The measure would assess the proportion of an ASC's health care workforce that has been vaccinated against COVID–19.

HCP are at risk of transmitting COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 infection themselves, and transmitting it to their families, friends, and the general public. We believe ASCs should report the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can reduce illness that leads to work absence and limit disruptions to providing care[314] with major reductions in SARS–CoV–2 infections among those receiving a two dose COVID–19 vaccine despite a high community infection rate.[315] Data from influenza vaccination demonstrate that provider vaccination is associated with that provider recommending vaccination to patients[316] and we believe HCP COVID–19 vaccination in ASCs could similarly increase vaccination among that patient population. We also believe that publishing the HCP vaccination rates will be helpful to many patients, particularly those who are at high-risk for developing serious complications from COVID–19, as they choose among ASCs for treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promote Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure (''COVID–19 HCP vaccination measure'') is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-LTC facilities including ASCs.

(a) Measure Specifications

The denominator for the HCP measure is the number of HCP eligible to work in the ASC for at least 1 day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[317]

The numerator for the HCP measure is the cumulative number of HCP eligible to work in at the ASC for at least 1 day during the reporting period and who received a complete vaccination course against COVID–19 using an FDA-authorized or FDA-approved vaccine for COVID–19 (whether the FDA issued an

[304] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on April 3, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/*.

[305] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. Accessed on June 2, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/21/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations-2/*.

[306] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[307] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[308] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/*.

[309] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f*.

[310] Centers for Disease Control and Prevention. Healthcare Workers. (2017) Accessed February 18, 2021 at: *https://www.cdc.gov/niosh/topics/healthcare/default.html*.

[311] KFF/The Washington Post Frontline Health Care Workers Survey. (2021). Accessed June 2, 2021 at: *https://www.kff.org/coronavirus-covid-19/poll-finding/kff-washington-post-health-care-workers/*.

[312] This information has been updated from the proposed rule to reflect current data from the Centers for Disease Control and Prevention. COVID Data Tracker. COVID–19 Vaccinations in the United States. Available at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations*.

[313] The White House. Remarks by President Biden Marking the 150 Millionth COVID–19 Vaccine Shot. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/*.

[314] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*.

[315] Benenson S, Oster Y, Cohen MJ, Nir-Paz R. BNT162b2 mRNA Covid–19 Vaccine Effectiveness among Health Care Workers. N Engl J Med. 2021. See also: Keehner J, Horton LE, Pfeffer MA, Longhurst CA, Schooley RT, Currier JS, et al. SARS–CoV–2 Infection after Vaccination in Health Care Workers in California. N Engl J Med. 2021.

[316] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[317] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed March 15, 2021 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications*.

approval or EUA).[318] A complete vaccination course is defined under the specific FDA authorization and may require multiple doses or regular revaccination.[319] Vaccination coverage for purposes of this measure is defined as the estimated percentage (given the potential for week-to-week variation) of HCP eligible to work at the ASC for at least 1 day who received a COVID–19 vaccine. For reporting, facilities would count HCP working in all facilities that share the same CMS certification number (CCN).[320] The proposed specifications for the COVID–19 HCP vaccination measure are available on the NQF website at: *https://www.cdc.gov/nhsn/nqf/index.html*.[321]

(b) Review by the Measure Applications Partnership

The COVID–19 HCP vaccination measure was included on the publicly available ''List of Measures Under Consideration for December 21, 2020,'' [322] a list of measures under consideration for use in various Medicare programs. The Measure Applications Partnership (MAP) hospital workgroup convened on January 11, 2021 and reviewed the Measures Under Consideration (MUC) List including the COVID–19 HCP vaccination measure. The MAP hospital workgroup agreed that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it could bring value to the ASCQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[323] The MAP hospital workgroup also stated in its recommendations that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to facilities will allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing COVID–19 infection rates in HCP may reduce transmission among patients and reduce instances of staff shortages due to illness.[324]

In its preliminary recommendations, the MAP hospital workgroup did not support this measure for rulemaking, subject to potential for mitigation.[325] To mitigate its concerns, the MAP hospital workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and National Quality Forum (NQF) endorsement prior to implementation.[326] Subsequently, the MAP Coordinating Committee met on January 25, 2021 and reviewed the COVID–19 HCP vaccination measure. In the 2020 and 2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measures back to MAP once the specifications are further refined.[327] The MAP stated, ''the incomplete specifications require immediate mitigation and further development should continue.'' [328] In its final report, the MAP noted that the measure would add value by providing visibility into an important intervention to limit COVID–19 infections in HCP and the patients for whom they provide care.[329] The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.[330] In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with the MAP Coordinating Committee on March 15, 2021. CMS and CDC provided additional information to address vaccine availability, alignment of the COVID–19 HCP vaccination measure as being as closely as possible with the data collection for the Influenza HCP vaccination measure (NQF #0431), and provided clarification on how HCP are defined. CMS and the CDC also presented preliminary findings from the testing of the numerator of the COVID–19 HCP vaccination measure, which is currently in process. These preliminary findings show numerator data should be feasible to collect and reliable. Testing of the measure numerator (the number of HCP vaccinated) involves a comparison of the data collected through the National Healthcare Safety Network (NHSN) and independently reported through the Federal pharmacy partnership program for delivering vaccination to LTC facilities. These are two independent data collection systems. In initial analyses of the first month of vaccination, the number of healthcare workers vaccinated in approximately 1,200 facilities for which data from both systems were available, the number of healthcare personnel vaccinated was highly correlated between the two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[331] Because of the high correlation across a large number of facilities and high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we believe the measure is feasible and reliable for use in ASCs. After reviewing this additional information, the MAP retained its final recommendation of conditional support, and expressed support for CMS' efforts to use the measure as part of the solution for the COVID–19 public health crisis.[332]

Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting certain quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as possible to address the urgency of the COVID–19 PHE and its impact on vulnerable populations. CMS continues to engage with the MAP to mitigate concerns and appreciates the MAP's conditional support for the measure.

(c) Measure Endorsement

Section 1833(i)(7)(B) of the Act states that section 1833(t)(17) of the Act shall apply with respect to ASC services in a similar manner in which it applies to hospitals for the Hospital OQR Program, except as the Secretary may otherwise provide. The requirements at section 1833(t)(17)(C)(i) of the Act state that measures developed shall ''be appropriate for the measurement of the quality of care (including medication

[318] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[319] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[320] Centers for Disease Control and Prevention. CMS Reporting Requirements FAQs. Accessed June 2, 2021 at: *https://www.cdc.gov/nhsn/PDFs/CMS/faq/FAQs-CMS-Reporting-Requirements.pdf*.

[321] *https://www.cdc.gov/nhsn/nqf/index.html*.

[322] *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[323] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[324] *Ibid.*

[325] *Ibid.*

[326] *Ibid.*

[327] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 3, 2021 at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*.

[328] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[329] *Ibid.*

[330] *Ibid.*

[331] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[332] *Ibid.*

errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.''

In general, we prefer to adopt measures that have been endorsed by the NQF because it is a national multi-stakeholder organization with a well-documented and rigorous approach to consensus development. However, as we have noted in previous rulemaking (for example, 75 FR 72065 and 76 FR 74494 for the Hospital OQR and ASCQR Programs, respectively), the requirement that measures reflect consensus among affected parties can be achieved in other ways, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

The proposed COVID–19 HCP vaccination measure is not NQF endorsed and has not been submitted to NQF for endorsement consideration. However, at this time, we find no other feasible and practicable measures on the topic of COVID–19 vaccination among HCP. CMS will consider the potential for future NQF endorsement as part of its ongoing work with the MAP. Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practicable measure has not been endorsed by the entity with a contract under section 1890(a) (currently the NQF), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Therefore, with the above considerations, we believe there is sufficient basis to propose adoption of this measure at this time.

(d) Data Collection, Submission, and Reporting

Given the time sensitive nature of this measure considering the current PHE, we are proposing that ASCs would be required to begin reporting data on the proposed COVID–19 HCP vaccination measure beginning January 1, 2022, for the CY 2024 payment determination for the ASCQR Program. Thereafter, we propose quarterly reporting periods. While we considered annual reporting periods for the ASCQR Program, we are proposing quarterly reporting periods given the immediacy of the PHE and the importance of alignment across quality payment programs proposing this measure.

If our proposal to adopt this measure is finalized, ASCs would report the measure through the CDC NHSN web-based surveillance system.[333] While the ASCQR Program does not currently require use of the NHSN web-based surveillance system, we have previously required use of this system for submitting program data. We refer readers to the CY 2014 OPPS/ASC final rule with comment period in which we adopted the Influenza Vaccination Coverage Among HCP (NQF #0431) measure (78 FR 75110 through 75117) and section XVI.D.1.c.(2). of this proposed rule for additional information on reporting through the NHSN web-based surveillance system under the ASCQR Program. The Influenza Vaccination Coverage Among HCP (NQF #0431) measure was removed from the ASCQR Program in the CY 2019 OPPS/ASC final rule as CMS observed that reporting measure data through the NHSN could be more burdensome for ASCs compared to the relative burden for hospitals participating in the Hospital IQR Program and the HAC Reduction Program and especially for freestanding ASCs (83 FR 59115 through 59117). However, the COVID–19 pandemic and associated PHE have had a more significant effect on most aspects of society than influenza, including availability of the healthcare system. With respect to reporting for the COVID–19 HCP vaccination measure, CDC guidance for entering data requires submission of HCP count at the facility level[334] and the measure requires reporting consistent with that guidance. We believe that the public health benefits to having these data available outweigh the burden of reporting for systems with multiple facilities or locations. While we recognize that there may be some elements of the measure specifications that increase burden for some ASCs, given the impact that the COVID–19 PHE has had on society and the healthcare system, we believe that the benefits outweigh this reporting burden. For more information on the associated burden of this measure, we refer readers to XXV.C.5.b. of the proposed rule.

To report this measure, we are proposing that ASCs would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one, self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet ASCQR Program requirements. While we believe that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that ASCs would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable estimate of vaccination levels among an ASC's HCP while balancing the costs of reporting. If an ASC submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we are proposing that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each ASC, which would be calculated by taking the average of the data from the three submission periods submitted by the ASC for that quarter. If finalized, CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

ASCs would submit the number of HCP eligible to have worked at the facility during the self-selected week that the ASC reports data in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week. As previously stated, facilities would count HCP working in all facilities that share the same CCN.[335]

We invite public comment on our proposal.

4. Proposed Changes to Previously Adopted Measures in the ASCQR Program Measure Set

We previously adopted the following measures into the ASCQR measure set: ASC–1: Patient Burn; ASC–2: Patient Fall; ASC–3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC–4: All-Cause Hospital Transfer/Admission; ASC–11: Cataracts—Improvement in Patient's Visual Function with 90 Days Following Cataract Surgery; and ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems. For various reasons discussed in sections XVI.B.4.a., XVI.B.4.b., and XVI.B.4.c., these measures were either paused or suspended from the ASCQR Program.

[333] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.* on February 10, 2021.

[334] COVID–19 Vaccination Non-LTC Healthcare Personnel TOI (*cdc.gov*).

[335] *Ibid.*

We now believe that previous concerns related to the data submission method previously utilized for these measures can be addressed and we are now proposing to return to requiring data submission for these measures.

a. Proposal To Require Previously Suspended ASC–1, ASC–2, ASC–3, and ASC–4 Measures Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and Subsequent Years

(1) Background

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. This outcome measure assesses the percentage of ASC admissions experiencing a burn prior to discharge. 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 (NQF #0266). This measure assesses the percentage of ASC admissions experiencing a fall at the ASC. 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 outcome measure assesses the percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant. 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 outcome measure assesses the rate of ASC admissions requiring a hospital transfer or hospital admission upon discharge from the ASC.

In the CY 2019 OPPS/ASC proposed rule, 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—for the CY 2021 payment determination and subsequent years (83 FR 37198 through 37199). We noted that the ASCQR Program had previously finalized two criteria for determining when a measure is ''topped-out,'' including: (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.[336] We presented data demonstrating that each of these four measures met the criteria for topped-out status and stated that we believed their removal from the ASCQR Program measure set was appropriate as there was little room for improvement. In addition, we stated that removal would alleviate the maintenance costs and administrative burden to ASCs associated with retaining the measures. As such, we believed the burden associated with reporting these measures outweighed the benefits of keeping them in the program (83 FR 37198 through 37199).

However, in the CY 2019 OPPS/ASC final rule with comment period, we stated that we had re-evaluated the data due to public comments and reviewed many studies demonstrating the importance of measuring and reporting the data for these measures (83 FR 59118). It became clear to us that these measures are more valuable to stakeholders than we had initially perceived. We agreed that it was 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 acknowledged that these measures provided critical data to beneficiaries and were valuable to the ASC community. We also acknowledged 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. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we did not finalize our proposals to remove ASC–1, ASC–2, ASC–3, and ASC–4 (83 FR 59118). We believed it was more prudent to keep them in the measure set in order to continue to detect and prevent these events.

However, we also stated in the CY 2019 OPPS/ASC final rule with comment period that we were concerned about some of the data submitted for these measures (83 FR 59119). We explained that the data submission method for these measures, which involved adding specific QDCs onto eligible claims, may impact the completeness and accuracy of the data. Specifically, we were concerned that ASCs lacked the ability to correct the QDC codes that are used to calculate these measures from Medicare FFS claims (83 FR 59119) if the claim had been submitted and processed for payment. We stated that we believed 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 (83 FR 59119).

Therefore, we suspended the data collection of ASC–1, ASC–2, ASC–3, and ASC–4 beginning with the CY 2019 reporting period/CY 2021 payment determination (83 FR 59119). Starting with the CY 2021 payment determination, facilities were not required to submit data for these four measures as part of ASCQR Program requirements, even though the measures remained in the ASCQR Program measure set. We stated that as we developed future revisions for the data collected for these measures, we would take into consideration other data submission methods that may allow for the reporting of adverse events across payers and would consider commenters' feedback toward the future updates to the measures (83 FR 59119).

(2) Proposal To Require ASC–1, ASC–2, ASC–3, and ASC–4 Measures Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and Subsequent Years

In this proposed rule, we are proposing to again require and resume data collection for ASC–1, ASC–2, ASC–3, and ASC–4 beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years. Under our proposal, providers would submit data via the HQR System (formerly referred to as the QualityNet Secure Portal). We believe that web-based submission will make reporting easier and more efficient for facilities and will allow facilities to review and correct submitted data until the data submission deadline; our review and corrections policy is discussed in more detail at section XVI.D.1.f.

We stated that we believed that revising the data submission method for

[336] In the CY 2019 OPPS/ASC proposed rule, we also clarified how we calculated the TCOV for ASC–1, ASC–2, ASC–3, and ASC–4, which assess the rate of rare, undesired events for which a lower rate is preferred. Typically, for measures for which a higher rate is preferred, we determine the TCOV by calculating the truncated standard deviation (SD) in performance divided by the truncated mean of performance (the mean of positive events). For these four measures, we employed an alternate methodology utilizing the mean of *non-adverse* events in our calculation of the TCOV. This substitution resulted in a TCOV that was comparable to that calculated for other measures and allowed us to assess rare event measures by still generally using our previously finalized topped-out criteria. For more information, see 83 FR 37196 through 37197.

the measures, such as via QualityNet (now known as the HQR System) would address this issue and allow facilities to correct any data submissions errors, resulting in more complete and accurate data (83 FR 59119). Facilities would be able to review and correct their data submissions up to the data submission deadline. As we stated above, we also believe that while these measures have been ''topped-out'', the public continues to believe that it is important to monitor these types of events, considering the potential negative impacts to patients' morbidity and mortality, to continue to prevent their occurrence and ensure that they remain rare.

We refer readers to section XVI.D.1.c.(1). of this proposed rule, where we discuss the data submission process for web-based measures, for more detail on how ASCs would be expected to submit data.

We invite public comment on our proposals.

b. Proposal To Require ASC–11: Cataracts—Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (NQF #1536) Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75124 through 75129) we finalized the adoption of the ASC–11: Cataracts—Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure.[337] This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery (78 FR 75129). The measure data consists of pre-operative and post-operative visual function surveys. The implementation of this measure underwent a number of changes aimed to address concerns regarding burden and survey instrument usage that we believe are resolved so that this measure can now be proposed as mandatory.

During the CY 2014 OPPS/ASC rule cycle, some commenters expressed concern about the burden of collecting pre-operative and post-operative visual function surveys (78 FR 75129 and 75138). In response to those comments, we modified our implementation strategy in a manner that we believed would significantly minimize collection and reporting burden (78 FR 75129). Specifically, we applied a sampling scheme and a low case threshold exemption to address commenters' concerns regarding burden (78 FR 75138 through 75139). With those changes, we intended to decrease burden and facilitate data reporting by allowing random sampling of cases when volume is high, instead of collecting information for all eligible patients (78 FR 75138 through 75139). For further details, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75129; 75138 through 75139).

Shortly thereafter, we became concerned about the use of what we believed at the time were inconsistent surveys to assess visual function. The measure specifications allowed for the use of any validated survey and we were unclear about the impact the use of varying surveys might have. Therefore, we issued guidance stating that we would delay the implementation of ASC–11.[338]

Subsequently, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985), we finalized our proposal to exclude ASC–11 from the CY 2016 payment determination measure set, and for subsequent years. We proposed to exclude ASC–11 for a few reasons. First, we understood it was operationally difficult for ASCs to collect and report on the measure (79 FR 66984). Notably, the results of the survey used to assess the pre-operative and post-operative visual function of the patient were not consistently shared across clinicians, making it difficult for ASCs to have knowledge of the visual function of the patient before and after surgery (79 FR 66984). Second, the concern about use of various versions of the survey persisted. Specifically, we were concerned that if physicians used different surveys to assess visual function, then the measure could produce inconsistent results (79 FR 66984).

By excluding ASC–11 from the measure set used for the CY 2016 payment determination and subsequent years, ASCs were excused from reporting on it (79 FR 66984). ASCs that did not report on ASC–11 for the CY 2016 payment determination were not subject to a payment reduction (79 FR 66984). In conjunction with excusing ASCs from reporting on ASC–11 for the CY 2016 payment determination and subsequent years, we finalized allowing ASCs to voluntarily report ASC–11 data for the CY 2015 reporting period/CY 2017 payment determination and subsequent years (79 FR 66984).

(2) Proposal To Require the ASC–11 Measure Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination and for Subsequent Years

We now believe it is appropriate to require that ASCs report on ASC–11 as our earlier concerns have been allayed. At this point, ASCs have had several years to familiarize themselves with ASC–11, prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period/CY 2017 payment determination. We note that a small number of facilities have consistently reported data for this measure and these data have been made publicly available. Furthermore, research indicates that using different surveys will not result in inconsistencies, as the allowable surveys are scientifically validated.[339] Research has demonstrated that of 16 different cataract surgery outcome questionnaires, all were able to detect clinically important change.[340]

Therefore, we are proposing to require reporting for the NQF-endorsed ASC–11 measure beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years. As we stated in the CY 2014 OPPS/ASC final rule with comment period, as well as the CY 2015 OPPS/ASC final rule with comment period, and consistent with the MAP recommendation, we continue to believe that this measure ''addresses a high-impact condition'' that is not otherwise adequately addressed in our current measure set (78 FR 75129 and 79 FR 66984, respectively). Moreover, ASC–11 serves to drive coordination of care (78 FR 75129 and 79 FR 66984) in multiple ways, including the operational requisites for conducting—and sharing the results of—the surveys. This measure provides opportunities for care

[337] We note that this measure was endorsed by the NQF under NQF #1536 at the time of adoption but has subsequently had its endorsement removed.

[338] The implementation was first delayed by 3 months—from January 1, 2014 to April 1, 2014, for the CY 2016 payment determination, via guidance issued December 31, 2013. Available at: *https://qualitynet.cms.gov/asc/notifications*. Because of continuing concerns, on April 2, 2014, we issued additional guidance stating that we would further delay the implementation of the measure from April 1, 2014 to January 1, 2015 for the CY 2016 payment determination. Available at: *https://qualitynet.cms.gov/asc/notifications*.

[339] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

[340] McAlinden C, Gothwal VK, Khadka J, Wright TA, Lamoureux EL, Pesudovs K. A head-to-head comparison of 16 cataract surgery outcome questionnaires. Ophthalmology. 2011 Dec;118(12):2374–81. doi: 10.1016/j.ophtha.2011.06.008. Epub 2011 Sep 25. PMID: 21945088.

coordination as well as direct patient feedback.

We refer readers to section XVI.D.1.c.(1). for information about submitting data via a CMS web-based tool. We invite public comment on our proposal.

c. Proposal To Require ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures Beginning With Voluntary Reporting in CY 2023 Reporting Period and Mandatory Reporting Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination and for Subsequent Years

(1) Background

We previously adopted the ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey-based measures to assess patient experience with care following a procedure or surgery in an ASC. These survey-based measures rate patient experience as a means for empowering patients and improving the quality of their care (82 FR 59450). For further details on this measure, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79803 through 79817), in which we adopted these measures beginning with the CY 2020 payment determination.

Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 49450 through 49451), we delayed implementation of ASC–15a–e for the ASCQR Program beginning with the CY 2020 payment determination due to lack of sufficient operational and implementation data. At that time, we believed that our ongoing National OAS CAHPS voluntary reporting program for the survey, which began in January 2016 [341] and is unrelated to either the Hospital OQR Program or ASCQR Program, would provide valuable information moving forward. Specifically, we wanted to use the information from the National OAS CAHPS voluntary reporting program to: (1) Ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; (2) reaffirm the reliability of national implementation of OAS CAHPS Survey data; and (3) appropriately account for the burden associated with administering the survey in the outpatient care setting.

Having had the opportunity during the delayed implementation to investigate the concerns about patient response rates and data reliability, we believe that patients are able to respond to OAS CAHPS questions, and that those responses are reliable based on prior experience collecting voluntary data for public reporting since CY 2016 (available at *https://www.medicare.gov/care-compare/*). We reaffirm that the OAS CAHPS survey-based measures assess important aspects of care where the patient is the best or only source of information (81 FR 79803). Regarding the burden associated with the survey, we believe that rating patient experience still provides important information to ASCs and patients, especially for assessing the quality of care provided at an ASC (82 FR 59450). Furthermore, in section XVI.D.1.d.(2)., we are proposing additional collection modes using a web-based module (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents) for administering the survey, which would be available beginning in CY 2023 under the ASCQR Program and for subsequent years.[342] We believe this would further address some burden concerns raised during the CY 2017 OPPS/ASC final rule with comment period (81 FR 59450) because the web-based modules may produce similar results but at lower costs of collection.[343] As we stated in the CY 2018 OPPS/ASC final rule with comment period, we continue to believe that implementation of these measures will enable objective and meaningful comparisons between ASCs (82 FR 59450) and that patient experience of care data is valuable in assessing the quality of care provided at an ASC and assisting patients in selecting a provider for their care (82 FR 59450).

In this proposed rule, we are proposing to restart the ASC–15a–e measures by proposing to link reporting of measure data with payment determinations as part of the ASCQR Program beginning with the CY 2024 reporting period/CY 2026 payment determination. Specifically, for the ASCQR Program, we are proposing voluntary data collection and reporting beginning with the CY 2023 reporting period, followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination. As noted above, the National OAS CAHPS voluntary reporting program is independent of the ASCQR Program and the Hospital OQR Program. This proposal is intended to make the distinction that ASCs that voluntarily report the OAS CAHPS survey-based measures during the CY 2023 reporting period would do so as part of the ASCQR Program until mandatory reporting begins, if these proposals are finalized. The reporting process for ASCs to submit OAS CAHPS data would remain unchanged for ASCs (that is, they would not duplicate submissions to the program and National OAS CAHPS voluntary reporting program) and we refer readers to section XVI.D.1.d. for our related proposals regarding the form, manner, and timing for reporting the ASC–15a–e survey-based measures.

We initially considered a 2-year voluntary period, that is, the CY 2023 and CY 2024 reporting periods, because we believed that ASCs may require additional preparation time for OAS CAHPS implementation including contracting with OAS CAHPS vendors. We also considered the challenges that many ASCs may have experienced during the COVID–19 pandemic and the additional operational constraints that they may still be experiencing. However, since voluntary reporting, including the two new modes of data collection we are proposing in section XVI.D.1.d.(2)., will be available in 2022 as part of the National OAS CAHPS voluntary reporting program, and we are proposing one year of voluntary reporting as part of the ASCQR Program for the CY 2023 reporting period, we believe that ASCs will have sufficient time to familiarize themselves with OAS CAHPS measures and OAS CAHPS vendors prior to mandatory reporting in the CY 2024 reporting period/CY 2026 payment determination and for subsequent years.

We refer readers to section XVI.D.1.d. for our related proposals regarding the form, manner, and timing for reporting the ASC–15a–e survey-based measures.

We invite public comment on our proposal. We also refer readers to section XV.B.5.a. of this proposed rule where we are also proposing to restart this measure in the Hospital OQR Program.

[341] Participation in the program is open to any interested Medicare-certified Hospital Outpatient Departments (HOPDs) and free-standing ambulatory surgery centers (ASCs). More information on the National OAS CAHPS voluntary reporting program is available at: *https://oascahps.org/General-Information/National-Implementation* and *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/OAS-CAHPS.*

[342] We note that the mixed modes will be available as part of the National OAS CAHPS voluntary reporting program beginning in CY 2022.

[343] Bergeson SC, Gray J, Ehrmantraut LA, Hays RD. Comparing Web-based with Mail Survey Administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Clinician and Group Survey. Prim Health Care. 2013 Sept; doi: 10.4172/2167–1079.1000132. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3783026/.*

5. Summary of Previously Finalized and Proposed ASCQR Program Quality Measure Set

a. Summary of Previously Finalized and Proposed ASCQR Program Quality Measure Set for the CY 2022 Reporting Period/CY 2024 Payment Determination

Table 52 summarizes the previously finalized and proposed ASCQR Program measure set for the CY 2022 reporting period/CY 2024 payment determination.

TABLE 52: Previously Finalized and Proposed ASCQR Program Measure Set for the CY 2022 Reporting Period/CY 2024 Payment Determination

ASC #	NQF #	Measure Name
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-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
	None	COVID-19 Vaccination Coverage Among Health Care Personnel**

† NQF endorsement was removed.
* The ASC-11 measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).
** We note that, if adoption finalized, an ASC/measure number will be assigned for this measure in the final rule.

b. Summary of Previously Finalized and Proposed ASCQR Program Quality Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination

Table 53 summarizes the previously finalized and proposed ASCQR Program measure set for the CY 2023 reporting period/CY 2025 payment determination.

TABLE 53: Previously Finalized and Proposed ASCQR Program Measure Set for the CY 2023 Reporting Period/CY 2025 Payment Determination

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-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
	None	COVID-19 Vaccination Coverage Among Health Care Personnel*

† NQF endorsement was removed.

* We note that, if adoption finalized, an ASC/measure number will be assigned for this measure in the final rule.

c. Summary of Previously Finalized and Proposed ASCQR Program Quality Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

Table 54 summarizes the previously finalized and proposed ASCQR Program measure set for the CY 2024 reporting period/CY 2026 payment determination and subsequent years.

TABLE 54: Previously Finalized and Proposed ASCQR Program Measure Set for the CY 2024 Reporting Period/CY 2026 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	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
	None	COVID-19 Vaccination Coverage Among Health Care Personnel*

† NQF endorsement was removed.

* We note that, if finalized, an ASC/measure number will be assigned for this measure in the final rule.

6. ASCQR Program Measures and Topics for Future Consideration

a. Request for Comment on Potential Adoption of Future Measures for the ASCQR Program

We seek to adopt a comprehensive set of quality measures for widespread use to inform decision-making regarding care and for quality improvement efforts in the ASC setting. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083 through 86110), under the OPPS we finalized the elimination of the Inpatient Only (IPO) list over a 3-year transitional period, beginning with the removal of approximately 300 primarily musculoskeletal-related services, with the list to be completely phased out by CY 2024.[344] As discussed in section IX. of this rule, we have continued to receive stakeholder requests to reconsider the elimination of the IPO list, to reevaluate services removed from the IPO list due to safety and quality concerns, and to, at a minimum, extend the timeframe for eliminating the list. After further consideration and review of the additional feedback from stakeholders, we believe that the timeframe we adopted for removing services from the IPO list does not give us a sufficient opportunity to carefully assess whether a procedure can be removed from the IPO list while still ensuring beneficiary safety. For CY 2022, we are proposing to halt the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021, we propose to add the 298 services removed from the IPO list in CY 2021 back to the IPO list beginning in CY 2022.

We are also proposing to reinstate the CY 2020 criteria used to add procedures to the ASC Covered Procedures List (CPL) and remove 258 of the additional 267 surgical procedures that were added to the ASC CPL beginning in CY 2021, under the CY 2021 revised criteria[345] with additional procedures being proposed for addition for CY 2022.

However, as technology and surgical techniques advance, services will continue to transition off of the IPO list, becoming payable in the outpatient hospital setting and being eligible for addition to the ASC covered procedures list in subsequent years. We recognize that there may be a need for more measures that inform decision-making regarding care and for quality improvement efforts, particularly focused on the behaviors of services that become newly eligible for payment in the ASC setting. In light of this, we seek comment on potential future adoption of measures that would allow better tracking of the quality of care for services that transition from the IPO list and may subsequently become eligible for addition to the ASC CPL.

Therefore, we invite public comment on the potential future adoption of measures for our consideration that address care quality in the ASC setting given the transition of procedures from inpatient settings to outpatient settings of care.

b. Request for Comment on Potential Future Adoption and Inclusion of an ASC-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

As described in section XVI.B.6.a. above, we are seeking comment on priorities for quality measurement in outpatient settings due to changes to the IPO procedure list (82 FR 59385 and 84

[344] Centers for Medicare & Medicaid Services. (2020, December 2). CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System final rule (CMS–1736–FC). Retrieved from *www.cms.gov/newsroom*: *https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0.*

FR 61355) and the ASC CPL (84 FR 61388 and 85 FR 86146).

We are also requesting comment on the potential future adoption of a re-specified version of a patient-reported outcome-based performance measure (PRO–PM) for two such procedures, elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA), which were removed from the IPO list effective for CY 2020 and CY 2018, respectively, and added to the ASC CPL effective for CY 2021 and CY 2020, respectively. We recently solicited public comment on the potential future inclusion of a Hospital-level THA/TKA PRO–PM (NQF #3559) in the FY 2022 IPPS/LTCH PPS proposed rule for the inpatient hospital setting (86 FR 25589). This measure reports the hospital-level risk-standardized improvement rate (RSIR) in patient-reported outcomes (PROs) following elective primary THA/TKA for Medicare fee-for-service (FFS) beneficiaries aged 65 years and older. Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning: (1) The Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients; and (2) the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk adjusted to account for differences in patient case mix. Potential non-response bias in measure scores due to the voluntary nature of PROs is incorporated in the measure calculation with stabilized inverse probability weighting based on likelihood of response.

Given the recent changes in the ASC CPL, we expect that THA and TKA procedures will increasingly be performed in ASCs and that the volume of these procedures on Medicare beneficiaries 65 and older will also increase in ASCs in future years.

We recognize that potential future adoption and implementation of a re-specified version of the THA/TKA PRO–PM in the ASCQR Program would require sufficient numbers of procedures for each measured ASC to ensure a reliable measure score. Only a subset of ASCs perform orthopedic procedures, so the measure would likely apply to a minority of ASCs. Additionally, implementing a THA/TKA PRO–PM would require providers to successfully collect pre- and post-operative PRO data for each procedure. Specifically, the inpatient THA/TKA PRO–PM discussed in the FY 2022 IPPS/LTCH PPS proposed rule requires a minimum of 25 cases with completed pre- and post-operative PRO data per hospital to ensure a reliable facility-level score. For more details on the inpatient THA/TKA PRO–PM, we refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25589) and the PROs Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

We will continue to monitor the number of THA and TKA procedures in ASCs and when we believe there is a sufficient number of such procedures performed in ASCs to reliably measure a meaningful number of facilities, we may consider expanding the PRO–PM to this setting. We also note that, as finalized in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59455 through 59463), the ASCQR Program currently includes a Hospital Visits After Orthopedic Ambulatory Surgical Center Procedures (ASC–17) measure using claims data which provides facilities with important information on patient outcomes for Medicare FFS beneficiaries following orthopedic surgery at ASCs and this measure includes THA and TKA procedures. The ASC–17 measure calculates a facility-specific risk-standardized hospital visit ratio within 7 days of an orthopedic procedure performed at an ASC and has as outcomes of interest unplanned hospital admissions, emergency department (ED) visits, and observation stays, thereby, providing valuable quality information for these procedures as they expand into the ASC setting.

As described in our Meaningful Measures 2.0 Framework, we aim to promote better collection and integration of patients' voices by developing PRO measures as an additional tool for measuring and improving quality. Given the unique challenges and opportunities for PRO–PMs for THA and TKA procedures in the ASC setting, we invite public comment on the potential future adoption of a re-specified version of PRO measures for elective THA/TKA PRO–PM for the ASCQR Program. Specifically, we invite public comment on the following:

- Input on the mechanism of PRO data collection and submission, including anticipated barriers and solutions to data collection and submission.
- Usefulness of having an aligned set of PRO–PMs across settings where elective THA/TKA are performed, that is, hospital inpatient setting, hospital outpatient departments, and ASCs for patients, providers, and other stakeholders. Specifically, usefulness and considerations for a healthcare system that performs inpatient and/or outpatient and ASC elective THA/TKAs.
- Considerations unique to THA/TKAs performed in the ASC setting such as the volume of procedures performed or the measure cohort, outcome, or risk adjustment approach.

We invite public comment on the adoption of a re-specified version of a PRO–PM measure for elective primary THA and TKA and future inclusion of such in the ASCQR Program measure set.

c. Request for Comment on Potential Future Efforts To Address Health Equity in the ASCQR Program

(1) Background

Significant and persistent inequities in health care outcomes exist in the U.S. Belonging to racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; and being near or below the poverty level, are often associated with worse health outcomes.[346] [347] [348] [349] [350] [351] [352] [353] Such

[346] Joynt K.E., Orav E., Jha A.K. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[347] Lindenauer P.K., Lagu T., Rothberg M.B., et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[348] Trivedi A.N., Nsa W., Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[349] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[350] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: *https://www.ruralhealthresearch.org/assets/2200–8536/rural-communities-age-income-health-status-recap.pdf.*

[351] U.S. Department of Health and Human Services Office of Minority Health. 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities, FY 2020. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[352] Heslin K.C., Hall J.E. Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity—Behavioral

Continued

disparities in health outcomes are the result of number of factors, but importantly for CMS programs, although not the sole determinant, negative experiences, poor access, and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[354 355 356 357 358 359] Readmission rates for common conditions in the Hospital Readmissions Reduction Program (HRRP) are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[360 361 362 363 364] Studies have also shown that African Americans are significantly more likely than White Americans to die prematurely from heart disease and stroke.[365] The COVID–19 pandemic has further highlighted many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to White persons.[366 367] As noted by the CDC, ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.'' [368] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[369] For the purposes of this proposed rule, we are using a definition of equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; LGBTQ+ persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [370] We note that this definition was recently established and provides a useful, common definition for equity across different areas of government, though numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Network Quality Improvement Organizations (QIN–QIOs); Federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[371]

We refer readers to the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25070) which summarizes our existing initiatives aimed at closing the equity gap in outcomes for Medicare beneficiaries. We also refer readers to the section XV.B.7.c.(1). of this proposed rule which describes the policy and statute which have informed the creation of the CMS Disparity Methods to provide confidential stratified results for measures in the hospital inpatient setting using dual eligibility as a proxy for social risk. Our efforts to stratify outcome measures by dual eligibility are supported by national recommendations from the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine, which identified dual eligibility, as an indicator of social risk, as a powerful predictor of poor health outcomes among the social risk factors that were tested.[372 373]

Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep 2021;70:149–154. DOI: *http://dx.doi.org/10.15585/mmwr.mm7005a1*. Available at: *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm*.

[353] Poteat T.C., Reisner S.L., Miller M., Wirtz A.L. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv*. 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[354] Martino, S.C., Elliott, M.N., Dembosky, J.W., Hambarsoomian, K., Burkhart, Q., Klein, D.J., Gildner, J., and Haviland, A.M. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[355] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf*.

[356] Singh J.A., Lu X., Rosenthal G.E., Ibrahim S., Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[357] Rivera-Hernandez M., Rahman M., Mor V., Trivedi A.N. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[358] Joynt K.E., Orav E., Jha A.K. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[359] Tsai T.C., Orav E.J., Joynt K.E. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[360] Rodriguez F., Joynt K.E., Lopez L., Saldana F., Jha A.K. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[361] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[362] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf*.

[363] Prieto-Centurion V., Gussin H.A., Rolle A.J., Krishnan J.A. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[364] Joynt K.E., Orav E., Jha A.K. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[365] HHS. Heart disease and African Americans.. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19*.

[366] CMS. Preliminary Medicare COVID–19 Data Snapshot. (April 16, 2021). Available at: *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf*.

[367] Ochieng N., Cubanski J., Neuman T., Artiga S., and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*.

[368] CDC. Health Equity Considerations & Racial & Ethnic Minority Groups. (April 19, 2021). Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html*.

[369] CMS. CMS Quality Strategy. (2016). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf*.

[370] Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. 86 FR 7009 (Jan. 20, 2021). Available at: *https://www.federalregister.gov/documents/2021/01/25/2021–01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*.

[371] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf*.

[372] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicaresvalue*-based-purchasing-programs.

[373] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

To date, we have not expanded disparities reporting to the ASC setting. Internally testing the two disparities methods (Within- and Across-Hospital Disparity Methods) on ASCQR Program quality measures calculated using Medicare FFS claims revealed several unique challenges to measuring disparities for dually eligible individuals in the ASC setting, principally, relatively low volumes of dual eligible patients in many facilities, and large diversity in the types and patient mix between ASCs as these facilities tend to specialize. In our initial analysis, few facilities met the minimum sample size required to yield technically feasible, adequately representative, and statistically reliable disparity results. We are considering social risk factors, including neighborhood-level social determinants of health, such as the poverty, education, and housing quality, which can adversely influence health outcomes, contributing to health inequities, in order to report more information regarding equity gaps in the care provided in the ASC setting. There are several different approaches for quantifying the health impacts of adverse neighborhood level socioeconomic factors. One approach is the Agency for Healthcare Research and Quality (AHRQ) neighborhood Socioeconomic Status (SES) Index, which uses information from the U.S. Census at the census block-group level to estimate the range of socioeconomic status in the beneficiary's neighborhood.[374] In this proposed rule, we are seeking comment on and are interested in learning more about the potential for measuring disparities in care provided in this setting.

(2) Solicitation of Public Comments

We are seeking comment on the possibility of providing equity reporting in the ASCQR Program in a way that maximally supports facilities in improving the quality of care for all Medicare beneficiaries, regardless of their socioeconomic status or other risk factors. We are particularly interested in learning about measurement approaches or social risk factors which may permit illuminating social-based disparities in facilities which have relatively few individuals who possess social risk factors. Specifically, we are inviting public comment on the following:

- Ways to address the unique challenges of measuring disparities in the ASC setting, such as small sample sizes, ASC specialization, and the relatively smaller proportion of patients with social risk factors.
- The utility of neighborhood-level socioeconomic factors toward measuring disparities in quality-of-care outcomes for ASCs.
- Ways social risk factors influence the access to care, quality of care and outcomes for ASC patients in general or for specific ASC services.

d. Request for Comment on the Future Development and Inclusion of a Pain Management Measure

Chronic pain is linked to a number of adverse physical and mental conditions [375] [376] [377] [378] and contributes to increased health care costs.[379] An estimated 20.4 percent (50 million) of U.S. adults have chronic pain.[380] As patients with acute and chronic pain continue to face challenges in obtaining adequate care,[381] Congress has advanced policies to improve the treatment of pain and substance use disorders. The Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114–198), the 21st Century Cures Act (Pub. L. 114–225), and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271) outline evidence-based national strategies and prevention toward reducing opioid dependence. In conjunction with the opioid epidemic efforts, the SUPPORT Act also provides guidelines for providers to be prepared to discuss pain management risks and options with patients, including providing referrals to a pain management specialist.[382] As a result of the opioid epidemic and as pain management procedures become more advanced, pain management practices and surgery centers have become increasingly viewed as feasible for the initial treatment of pain as well as for the expansion of non-opioid treatments for pain management.[383] Based on a growing body of evidence on the risks of opioid misuse, we have developed a strategy to impact the national opioid misuse epidemic by combating nonmedical use of prescription opioids, opioid use disorder, and overdose through the promotion of safe and appropriate opioid utilization, improved access to treatment for opioid use disorders, and evidence-based practices for acute and chronic pain management.[384]

With advances in techniques and growing recognition by providers that pain is a treatable condition, pain management services have seen rapid growth as a form of early intervention [385] and more such procedures are being performed in ASCs.[386] ASCs specializing in pain management services are also growing

[374] Bonito A.J., Bann C., Eicheldinger C., Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

[375] Institute of Medicine (US) Committee on Pain, Disability, and Chronic Illness Behavior; Osterweis M, Kleinman A, Mechanic D, editors. Washington (DC): National Academies Press (US); 1987. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK219250/*.

[376] Hooten W.M. Chrnoic Pain and mental Health Disorders: Shared Neural Mechanisms, Epidemiology, and Treatment. (2016). May Clinic Proceedings. Available at: *https://www.mayoclinicproceedings.org/article/S0025-6196(16)30182-3/fulltext*.

[377] De Heer E.W., Gerrits MMJG., Beekman ATF., Dekker J., van Marwijk HWJ., de Waal MWM., Spinhoven P., Penninx BWJH., van der Feltz-Cornelis C.M. (2014). The Association of Depression and Anxiety with Pain: A Study for NESDA. PLOS ONE 9(12): e115077. *https://doi.org/10.1371/journal.pone.0115077*.

[378] Rayner L., Hotopf M., Petkova H., Matcham F., Simpson A., and McCracken L.M. (2016). Depression in patients with chronic pain attending a specialised pain treatment centre: Prevalence and impact on health care costs. Pain; 157(7): 1472–1479. doi: 10.1097/j.pain.0000000000000542.

[379] Gaskin D.J. and Richard P. (2012). The Economic Costs of Pain in the United States. The Journal of Pain; 13(8): 715–724. Available at: *https://www.jpain.org/article/S1526-5900(12)00559-7/pdf#:~:text=The%20additional%20health%20care%20costs,from%20%24299%20to%20%24335%20billion*.

[380] Dahlhamer J., Lucas J., Zelaya, C., et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults—United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001–1006. DOI: *http://dx.doi.org/10.15585/mmwr.mm6736a2*.

[381] *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf*.

[382] H.R.6—SUPPORT for Patients and Communities Act. Available at: *https://www.congress.gov/bill/115th-congress/house-bill/6/text*.

[383] MedPac. Report to the Congress: Medicare Payment Policy, Chapter 16: Opioids and alternatives in hospital settings—Payments, incentives, and Medicare data. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch16_sec.pdf?sfvrsn=0*.

[384] CMS Opioid Misuse Strategy 2016. Available at: *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Prescription-DrugInformation-for-Partners-Items/CMS-OpioidMisuse-Strategy-2016.html*.

[385] Manchikanti, L., Parr A., Singh V., Fellows B. Ambulatory Surgery Centers and Interventional Techniques: A Look at Long-Term Survival. Pain Physician 2011; 14: E177–215. Available at: *https://www.painphysicianjournal.com/current/pdf?article=MTQ1MQ%3D%3D&journal=60*.

[386] Manchikanti, L., Parr A., Singh V., Fellows B. Ambulatory Surgery Centers and Interventional Techniques: A Look at Long-Term Survival. Pain Physician 2011; 14: E177–215. Available at: *https://www.painphysicianjournal.com/current/pdf?article=MTQ1MQ%3D%3D&journal=60*.

as a share of overall ASCs.[387] The most common multispecialty ASCs that focused on two specialties in 2017 were those specializing in pain management and either neurology or orthopedic services.[388]

We internally analyzed CY 2019 and CY 2020 Medicare FFS claims data using the methodology previously adopted for the ASC–7: ASC Facility Volume Data on Selected ASC Surgical Procedures measure (76 FR 74507 through 74509), which identifies procedure categories for the top 100 current procedural terminology (CPT®) codes reimbursed (we refer readers to Table 55). In our analyses of the Medicare FFS claims data from CY 2019 and CY 2020, we found that overall, the number of procedures declined 22 percent, likely reflecting conditions imposed by the COVID–19 PHE. The rank ordering of the types of procedures performed remained constant for the most part with pain management procedures (contained in the Nervous System category) being the third most commonly performed procedure category with 22.3 percent and 22.6 percent in CY 2019 and CY 2020, respectively.

TABLE 55. ASC Procedures from Medicare FFS Claims for CY 2019 and CY 2020 Based on CPT Codes

CY 2019				CY 2020				% Decline CY 2019 to CY 2020
Procedure Category	# of CPTs	# of Procedures	% of Total Procedures	Procedure Category	# of CPTs	# of Procedures	% of Total Procedures	
Gastrointestinal	15	1,895,911	32.9%	Gastrointestinal	15	1,479,220	32.5%	22.0%
Eye	19	1,864,585	32.3%	Eye	19	1,469,128	32.2%	21.2%
Nervous System	22	1,287,131	22.3%	Nervous System	22	996,813	21.9%	22.6%
Musculoskeletal	14	265,967	4.6%	Musculoskeletal	15	233,791	5.1%	12.1%
Genitourinary	8	169,470	2.9%	Genitourinary	8	143,894	3.2%	15.1%
Skin	8	119,329	2.1%	Skin	9	95,001	2.1%	20.4%
Imaging	7	89,075	1.5%	Imaging	6	66,939	1.5%	24.9%
Dialysis-related	3	51,102	0.9%	Dialysis-related	3	54,749	1.2%	-7.1%
Respiratory	3	20,330	0.4%	Respiratory	2	11,562	0.3%	43.1%
Anesthesia	1	6,635	0.1%	Anesthesia	1	6,062	0.1%	NA
Total	100	5,769,535	100.0%		100	4,557,159	100.0%	22.0%

Thus, we see pain management surgical procedures as a significant portion of procedures performed in the ASC setting and that an applicable measure would provide important quality of care information for a specialty not included in the current ASCQR Program measure set.

We invite public comment on the development and future inclusion of a measure to assess pain management surgical procedures performed in ASCs.

7. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CYs 2012, 2013, 2014, 2015, and 2016 OPPS/ASC final rules with comment period (76 FR 74513 through 74514; 77 FR 68496 through 68497; 78 FR 75131; 79 FR 66981; and 80 FR 70531, respectively) for detailed discussion of our policies regarding the maintenance of technical specifications for the ASCQR Program which are codified at 42 CFR 416.325. We are not proposing any changes to these policies in this proposed rule.

We also refer readers to section XIV. of this proposed rule where we request information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the Fast Healthcare Interoperability Resources (FHIR) standard (as described in that section).

8. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017, and 2018 OPPS/ASC final rules with comment period (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 through 79820; and 82 FR 59455 through 59470, respectively) for detailed discussion of our policies regarding the public reporting of ASCQR Program data, which are codified at 42 CFR 416.315 (80 FR 70533). We are not proposing any changes to these policies in this proposed rule.

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 the maintenance of a QualityNet account and security administrator for the ASCQR Program at § 416.310(c)(1)(i). In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86189), we finalized the use of the term ''security official'' instead of ''security administrator'' to denote the

[387] MedPac. Report to the Congress: Medicare Payment Policy, Chapter 5: Ambulatory Surgical Center Services. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0.*

[388] Report to the Congress: Medicare Payment Policy, Ambulatory Surgical Center Services. March 2019. Available at: *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch5_sec.pdf?sfvrsn=0.*

exercise of authority invested in the role. The term ''security official'' refers to ''the individual(s)'' who have responsibilities for security and account management requirements for a facility's QualityNet account. We are not proposing any changes to this policy in this proposed rule.

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 through 70534), we codified these requirements regarding participation status for the ASCQR Program at § 416.305. We are not proposing any changes to these policies in this proposed rule.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Data Collection and Submission

a. Background

We previously codified our existing policies regarding data collection and submission under the ASCQR Program at § 416.310.

b. Requirements for Claims-Based Measures

(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 § 416.310(a)(1) and (2). We note that the previously finalized data processing and collection period requirements will apply to any future claims-based-measures using QDCs adopted in the ASCQR Program. We are not proposing any changes to these requirements in this proposed rule.

(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. As noted in section XVI.D.1.b., our policies for minimum threshold, minimum case volume, and data completeness requirements will apply to any future claims-based-measures using QDCs adopted in the ASCQR Program. We are not proposing any changes to these policies in this proposed rule.

(3) Requirements Regarding Data Processing and Collection Periods for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59136 through 59138) for a complete summary of the data processing and collection requirements for the non-QDC based, claims-based measures. We codified the requirements regarding data processing and collection periods for non-QDC, claims-based measures for the ASCQR Program at § 416.310(b). We note that these requirements for non-QDC based, claims-based measures apply to the following previously adopted measures:

- ASC–12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; and
- ASC–19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357).

We are not proposing any changes to these requirements in this proposed rule.

c. Requirements for Data Submitted via an Online Data Submission Tool

(1) 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 HQR System (formerly referred to as the QualityNet Secure Portal) to host our CMS online data submission tool, available at: *https://qualitynet.cms.gov/*. 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 at § 416.310(c)(1)(i). We are not proposing any changes to these policies for data submitted via a CMS online data submission tool in this proposed rule.

The following previously finalized measures 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; and
- ASC–14: Unplanned Anterior Vitrectomy.

As discussed in section XVI.B.4.a.(2). of this proposed rule, we are proposing to require and resume data collection beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years for the following four 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.

Measure data for these measures would be submitted via the HQR System (formerly referred to as the QualityNet Secure Portal).

(2) 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 (specifically, the CDC NHSN website). We codified our existing policies regarding the data collection periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at § 416.310(c)(2). While we are not proposing any changes to those policies in this proposed rule, we are proposing policies specific to the proposed COVID–19 Vaccination Coverage Among HCP measure, for which data would be submitted via the CDC NHSN website.

(a) Proposed Form, Manner, and Timing for the COVID–19 Vaccination Coverage Among HCP Measure Beginning With the CY 2022 Reporting Period/CY 2024 Payment Determination and Subsequent Years

For the COVID–19 Vaccination Coverage Among HCP measure, we are proposing to require reporting data on the number of HCP who have received the completed vaccination course of a COVID–19 vaccine by each individual facility's CMS CCN.

We propose that ASCs would report the measure through the NHSN web-based surveillance system.[389] Specifically, ASCs would use the COVID–19 vaccination data reporting modules in the NHSN HPS Component to report the number of HCP eligible to have worked at the ASC that week (denominator) and the number of those HCP who have received COVID–19 vaccination (numerator). Specific details on data submission for this measure can be found in the CDC's Overview of the Healthcare Safety Component, available at: *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf*.

For the COVID–19 Vaccination Among HCP measure, we are proposing that ASCs would report the measure to the NHSN for at least one week each month, beginning with the January 1, 2022, through December 31, 2022, reporting period affecting CY 2024 payment determination and continuing with quarterly reporting deadlines for subsequent years. If ASCs report more than one week of data in a month, the most recent week's data would be used for measure calculation purposes. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the reporting periods for the quarter.

With respect to public reporting, this quarterly average COVID–19 vaccination coverage would be publicly reported on the *Care Compare* website in four-quarter increments, when four quarters of data are available. Once four quarters are available, data will be refreshed on a quarterly basis with the most recent four quarters publicly displayed. For each CMS CCN, a percentage of the HCP who received a complete course of the COVID–19 vaccine would be calculated and publicly reported. We invite public comment on our proposal.

[389] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

d. Proposed Form, Manner, and Timing for Reporting the ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

(1) Background

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79824) 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 59450 through 59451), where we finalized a policy to delay implementation of the ASC–15a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking.

(2) Proposal To Add Data Collection Survey Modes of OAS CAHPS Measures Collection to Existing Three Modes

As discussed in section XVI.B.4.c. of this proposed rule, we are proposing to begin data collection of five survey-based measures derived from the OAS CAHPS Survey for the ASCQR Program beginning with voluntary reporting for the CY 2023 reporting periods/CY 2025 payment determination,[390] followed by mandatory data collection and reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years. The OAS CAHPS survey contains three OAS CAHPS composite survey-based measures and two global survey-based measures. In this section, we are proposing requirements related to survey administration, vendors, and oversight activities.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79825), we previously discussed the time, form, and manner which OAS CAHPS information will be submitted. We are now proposing two additional data collection modes (web with mail follow-up of non-respondents and web with telephone follow-up of non-respondents)[391] beginning with voluntary data collection and reporting for the CY 2023 reporting/CY 2025 payment determination and continuing for mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination and for subsequent years, if finalized in section XVI.B.4.c. For more information about the modes of administration, we refer readers to the OAS CAHPS website: *https://oascahps.org*. We reiterate our clarification from when we adopted these measures in the CY 2017 OPPS/ASC final rule that, when implemented, ASCs that anticipate receiving more than 300 surveys would be required to either: (1) Randomly sample their eligible patient population; or (2) survey their entire OAS CAHPS eligible patient population (81 FR 79809). We also refer readers to section XV.D.4.b of this proposed rule where we describe our similar policy for the Hospital OQR Program.

[390] As stated in section XVI.B.4.c., we note that National OAS CAHPS voluntary reporting is independent of the ASCQR Program, but the submission process will otherwise remain unchanged. This proposal is intended to clarify that voluntary reporting of OAS CAHPS would begin as part of the ASCQR program in the CY 2023 reporting period until mandatory reporting would begin in the CY 2024 reporting period, if both proposals are finalized.

(a) Survey Requirements

The data collection for the survey currently has three administration methods: (1) Mail-only; (2) telephone-only; and (3) mixed mode (mail with telephone follow-up of non-respondents). We refer readers to the Protocols and Guidelines Manual for the OAS CAHPS Survey (*https://oascahps.org/Survey-Materials*) for materials for each mode of survey administration. In the 2018 OPPS/ASC final rule with comment period, we expressed interest in investigating the feasibility of offering the OAS CAHPS Survey using a web-based format (82 FR 59451). As a result, we designed a mode experiment to assess the impact of adding web-based survey administration. This mode experiment tested five administration modes with patients who receive outpatient surgical care: (1) Mail-only; (2) telephone-only; (3) web-only; (4) web with mail follow-up; and (5) web with a telephone follow-up. Data collection was completed in the fall of 2019. Response rates by mode in the experiment were: 35 percent (mail-only); 19 percent (telephone-only); 29 percent (web-only); 39 percent (web with mail follow-up); and 35 percent (web with telephone follow-up).

Based on these results, in addition to the three previously established modes, in this proposed rule we are proposing to incorporate two additional administration methods: (1) Web with mail follow-up of non-respondents; and

[391] The two additional modes will be available as part of National OAS CAHPS voluntary reporting in 2022.

(2) web with telephone follow-up of non-respondents. This would allow a total of five modes of survey administration for reporting beginning with voluntary data collection and reporting as part of the ASCQR Program for the CY 2023 reporting period [392] and continuing for mandatory data collection and reporting for the CY 2024 reporting period/CY 2026 payment determination—the first year the survey would be required if our proposal in section XVI.B.4.c. is finalized as proposed—and thereafter. We are not proposing a purely web-based format at this time because the use of a web-based mode is included in the two mixed modes options being proposed and the purely web-based format would create response bias since not all patients have the ability to respond by web.

For all five proposed modes of administration as part of the ASCQR Program, we are proposing that data collection must be initiated no later than 21 calendar days after the month in which a patient has a surgery or procedure at an ASC and completed within 6 weeks (42 days) after initial contact of eligible patients begins, beginning with voluntary data collection and reporting in the CY 2023 reporting period/CY 2025 payment determination and subsequent years. Under this proposal, ASCs, via their CMS-approved survey vendors, must make multiple attempts to contact eligible patients unless the patient refuses or the ASC/vendor learns that the patient is ineligible to participate in the survey. In addition, we are proposing that ASCs, via their CMS-approved survey vendor, collect survey data for eligible patients using the established quarterly deadlines to report data to CMS for each data collection period, unless the ASC has been exempted from the OAS CAHPS Survey requirements under our minimum case volume for program participation [393] or our OAS CAHPS low-volume exemption policy, which exempts ACS that treat fewer than 60 survey-eligible patients during the ''eligibility period,'' (which is the calendar year before the data collection period (81 FR 79806)), that submit the participation exemption request form, which will be made available on the OAS CAHPS Survey website (*https://oascahps.org*) on or before May 15 of the data collection year. As finalized previously, all exemption requests would be reviewed and evaluated by CMS (81 FR 79806). For ASCs with minimum case volumes, but without a low-volume exemption, these submission deadlines would be posted on the OAS CAHPS Survey website (*https://oascahps.org*). Late submissions would not be accepted.

As discussed in more detail below, compliance with the OAS CAHPS Survey protocols and guidelines, including this monthly data collection requirement as part of each quarterly data submission, would be overseen by CMS or its contractor who would receive approved vendors' monthly submissions, review the data, and analyze the results. As stated previously (81 FR 79805), all data collection and submission for the OAS CAHPS Survey measures would be reported at the CCN level, and if data collection and reporting becomes mandatory in CY 2024 reporting period/CY 2026 payment determination as proposed, under this proposal, all eligible ASCs in a CCN would be required to participate in the OAS CAHPS Survey, except for those that meet and receive an exception for having fewer than 60 survey-eligible patients during the year preceding the data collection period (81 FR 79806). Therefore, the survey data reported for a CCN must include eligible patients from all eligible ASCs covered by the CCN; or if more than 300 completed surveys are anticipated, an ASC can choose to randomly sample their eligible patient population (81 FR 79817).

In this proposed rule, we also propose that survey vendors acting on behalf of ASCs must submit data by the specified data submission deadlines, which generally would be posted on the Outpatient and Ambulatory Surgery CAHPS Survey website located at *https://oascahps.org/Data-Submission/Data-Submission-Deadlines*. If an ASC's data are submitted after the data submission deadline, it would not fulfill the OAS CAHPS quality reporting requirements. Therefore, in regard to any OAS CAHPS reporting, we would strongly encourage ASCs to be fully appraised of the methods and actions of their survey vendors, especially the vendors' full compliance with OAS CAHPS Survey administration protocols, and to carefully inspect all data warehouse reports in a timely manner.

We reiterate that the use of predictive or auto dialers in telephonic survey administration is governed by the Telephone Consumer Protection Act (TCPA) (47 U.S.C. 227) and subsequent regulations promulgated by the Federal Communications Commission (FCC) (47 CFR 64.1200) and Federal Trade Commission. We refer readers to the FCC's declaratory ruling released on July 10, 2015 further clarifying the definition of an auto dialer, available at: *https://apps.fcc.gov/edocs_public/attachmatch/FCC–15–72A1.pdf*. In the telephone-only and mixed mode survey administration methods involving telephone, ASCs and vendors must comply with the regulations discussed above, and any other applicable regulations. To the extent that any existing CMS technical guidance conflicts with the TCPA or its implementing regulations regarding the use of predictive or auto dialers, or any other applicable law, CMS would expect vendors to comply with applicable law.

We invite comments on our proposals discussed previously.

(b) Vendor Requirements

We are not proposing new vendor requirements, but reiterate the vendor requirements finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79823 through 79824) to ensure that patients respond to the survey in a way that reflects their actual experiences with outpatient care, and is not influenced by the ASC. We finalized that ASCs must contract with a CMS-approved OAS CAHPS Survey vendor to conduct or administer the survey. We believe that a neutral third-party should administer the survey for ASCs, and it is our belief that an experienced survey vendor will be best able to ensure reliable results. CAHPS Survey-approved vendors are also already used or required in the following CMS quality programs: The Hospital Inpatient Quality Reporting Program (71 FR 68203 through 68204); the Hospital Value-Based Purchasing (VBP) Program (76 FR 26497, 26502 through 26503, and 26510); the End Stage Renal Disease Quality Improvement Program (76 FR 70269 through 70270); the Home Health QRP (80 FR 68709 through 68710); and the Hospice QRP (80 FR 47141 through 47207).

Information about the list of approved survey vendors and how to authorize a vendor to collect data on an ASC's behalf is available through the OAS CAHPS Survey website, available at: *https://oascahps.org*. The web portal has both public and secure (restricted access) sections to ensure the security and privacy of selected interactions. As

[392] As stated in section XVI.B.4.c., we note that the two modes (web with mail follow-up of non-respondents; and web with telephone follow-up of non-respondents) will be available beginning in CY 2022 for National OAS CAHPS voluntary reporting, and then if finalized, available as part of ASCQR Program beginning in the CY 2023 reporting period and subsequent years.

[393] ASCs with fewer than 240 Medicare claims (Medicare primary and secondary payer) per year during an annual reporting period for a payment determination year are not required to participate in the ASCQR Program for the subsequent annual reporting period for that subsequent payment determination year. See 42 CFR 416.305.

mentioned earlier, requirements for survey vendors were previously finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79793 through 79794) and codified at § 416.310(e)(2). ASCs will need to register on the OAS CAHPS Survey website (*https://oascahps.org*) in order to authorize the CMS-approved vendor to administer the survey and submit data on their behalf. Each ASC must then administer (via its vendor) the survey to eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (*https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website.

e. ASCQR Program Data Submission Deadlines

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191) we finalized that all program deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Act, 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days.'' Specifically, the Act indicates that all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day, all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order, shall be extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order (42 U.S.C. 416(j)). We codified this policy at § 416.310(f). We are not proposing any changes to this policy in this proposed rule.

f. Review and Corrections Period for Measure Data Submitted to the ASCQR Program

(1) Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool

Under the ASCQR Program, for measures submitted via a CMS online data submission tool, ASCs submit measure data to CMS from January 1 through May 15 during the calendar year subsequent to the current data collection period (84 FR 61432).[394] For example, ASCs collect measure data from January 1, 2020 through December 31, 2020 and submit these data to CMS from January 1, 2021 through May 15, 2021. ASCs may begin submitting data to CMS as early as January 1. ASCs are encouraged, but not required, to submit data early in the submission period so that they can identify errors and resubmit data before the established submission deadline.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86191 through 86192), we finalized the formalization of that process and established a review and corrections period similar to what was finalized for the Hospital OQR Program in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86184) for data submitted via the CMS web-based tool. For the ASCQR Program, we finalized the implementation of a review and corrections period which runs concurrently with the data submission period beginning with the effective date of this rule. During this review and corrections period, ASCs may enter, review, and correct data submitted directly to CMS. However, after the submission deadline, ASCs are not allowed to change these data. We codified this review and corrections period at § 416.310(c)(1)(iii). We are not proposing any changes to this policy in this proposed rule.

(2) Review and Corrections Period for the OAS CAHPS Measures

Each ASC administers (via its vendor) the survey to all eligible patients treated during the data collection period on a monthly basis according to the guidelines in the Protocols and Guidelines Manual (available at: *https://oascahps.org*) and report the survey data to CMS on a quarterly basis by the deadlines posted on the OAS CAHPS Survey website as stated above in section XVI.D.1.d.(2).(b). Data cannot be altered after the data submission deadline but can be reviewed prior to the submission deadline (81 FR 79822 through 79823).

g. 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. We are not proposing any changes to this policy in this proposed rule.

h. Extraordinary Circumstances Exception (ECE) Process for the CY 2021 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 § 416.310(d) of our regulations to reflect this change. We will strive to complete our review of each request within 90 days of receipt. We are not proposing any changes to this policy in this proposed rule.

E. Proposed Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to 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 are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2022, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023). 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 finalized proposal to update the ASC

[394] ASCQR Program Data Submission Deadlines. Available at: *https://qualitynet.cms.gov/asc/data-submission#tab2.*

payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

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 productivity 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 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 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 when provided integral to covered ASC surgical procedures. 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 through CY 2021 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We propose the continuation of these policies for CY 2022.

XVII. Request for Information on Rural Emergency Hospitals

A. Background

Americans who live in rural areas of the nation make up about 20 percent of the United States population, and they often experience shorter life expectancy, higher all-cause mortality, higher rates of poverty, fewer local doctors, and greater distances to travel to see healthcare providers, than do their urban and suburban counterparts.[395]

The healthcare inequities that many rural Americans face raise serious concerns that the trend for poor healthcare access and worse outcomes overall in rural areas will continue unless the potential causes of such healthcare inequities are addressed.

In addition, one in five rural residents identifies as Black, Hispanic, American Indian/Alaska Native (AI/AN), Asian American/Pacific Islander (AA/PI), or a combination of ethnic backgrounds. Compared to the non-Hispanic White rural population, these minority groups often and regularly experience several disadvantageous social determinants of health.[396]

Rural hospitals are essential to providing health care to their communities and the closure of these hospitals limits access to care for the communities they once served and reduces employment opportunities, further impacting local economies. Barriers to accessing health services can

[395] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[396] Rural Health Research Gateway. (2020). Rural Ethnic/Racial Disparities: Adverse Health Outcomes. *https://www.ruralhealthresearch.org/assets/3973-16600/rural-ethnic-racial-disparities-health-recap.pdf.*

lead to unmet health needs, delays in receiving appropriate care, inability to get preventive services, financial burdens, and preventable hospitalizations.[397] Healthcare workforce shortages can also significantly impact healthcare access in rural communities.[398] As of March 2021, 61.47 percent of Primary Medical Health Professional Shortage Areas (HPSAs) were located in rural areas.[399]

The Consolidated Appropriations Act (CAA), 2021, was signed into law in December 2020. In this legislation, Congress established a new Medicare provider type: Rural Emergency Hospitals (REHs). Section 125 of the CAA, 2021, Division CC, defines an REH as a facility that: Is enrolled in the Medicare program on or after January 1, 2023; does not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)); has a transfer agreement in effect with a level I or level II trauma center; meets certain licensure requirements; meets requirements to be a staffed emergency department; meets staff training and certification requirements established by the Secretary; and meets certain conditions of participation (CoPs) applicable to hospital emergency departments and critical access hospitals (CAHs) with respect to emergency services. CAHs and small rural hospitals that convert to REHs may furnish rural emergency hospital services for Medicare payment beginning in 2023.

The Secretary is required to establish quality measurement reporting requirements for REHs, which may include claims-based measures and/or patient experience surveys. An REH is required to submit quality measure data to the Secretary, and the Secretary shall establish procedures to make the data available to the public on the CMS website.

The Quality Improvement Organization requirements established at section 1156(a) of the Social Security Act (the Act) shall apply to REHs in the same manner that they apply to hospitals and CAHs, in accordance with section 125(b)(1) of the CAA. In addition, the requirements established at section 1864 of the Act for hospitals and CAHs to be surveyed for compliance with the CoPs shall apply to REHs in the same manner as other hospitals and CAHs, in accordance with section 125(d)(2) of the CAA.

Additionally, section 125 of the CAA, 2021, requires that REHs provide emergency department services and observation services, and, at the election of the REH, other medical and health services furnished on an outpatient basis, as specified by the Secretary. The REH must also have a staffed emergency department 24 hours a day, 7 days a week, with staffing requirements similar to those for CAHs.[400]

In order to become an REH, a provider must, on the date of enactment of the CAA, 2021 (December 27, 2020), either already be a CAH or a rural subsection (d) hospital with not more than 50 beds. In addition, the REH must meet certain other requirements, including, but not limited to the following:

- An annual per patient average of 24 hours or less in the REH;
- staff training and certification requirements established by the Secretary;
- emergency services CoPs applicable to CAHs;
- hospital emergency department CoPs determined applicable by the Secretary;
- the applicable SNF requirements (if the REH includes a distinct part SNF);
- a transfer agreement with a level I or level II trauma center; and
- any other requirements the Secretary finds necessary in the interest of the health and safety of individuals who are furnished REH services.

Starting on January 1, 2023, an REH that provides rural emergency hospital services (as defined in section 1861(kkk)(1) of the Act) will receive a Medicare payment for those services pursuant to section 1843(x)(1) of the Act that reflects a 5 percent increase over the payment rate the provider would otherwise receive through the OPPS. Any co-payments for these services will be calculated based on the standard OPPS rate for the service excluding the 5 percent payment increase.

REHs also will receive an additional facility payment pursuant to section 1834(x)(2) of the Act. The annual payment amount will be determined based on the excess (if any) of the total amount that was paid to all CAHs in 2019 over the estimated total amount that would have been paid to CAHs in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during such year. This excess amount is divided by the total number of CAHs in 2019. After the initial Medicare subsidy amount is calculated for CY 2023, the additional facility payments in subsequent years will increase by the hospital market basket percentage increase. REHs will receive these additional facility payments in twelve monthly installments. REHs also will be required to maintain detailed information as to how they have used these payments.

B. Solicitation of Public Comments

Under the statute, in addition to the applicable mandatory CAH requirements (42 CFR part 485, subpart F), hospital emergency services requirements (42 CFR 482.55) and SNF requirements (42 CFR part 483, subpart B), the Secretary has discretion to determine what, if any, additional health and safety requirements should apply to REHs. We are soliciting stakeholder input as we consider the health and safety standards that, in accordance with the statute, should apply to REHs in order for them to be certified to participate in the Medicare program. We are also seeking broad input on the concerns of rural providers that should be taken into consideration by CMS in establishing additional CoPs for REHs. Specifically, we are asking for stakeholder input on the following questions:

Type and Scope of Services Offered

1. What are the barriers and challenges to delivering emergency department services customarily provided by hospitals and CAHs in rural and underserved communities that may require different or additional CoPs for REHs (for example, staffing shortages, transportation, and sufficient resources)?

2. An REH must provide emergency and observation services and may elect to provide additional services as determined appropriate by the Secretary. What other outpatient medical and health services, including behavioral health services, should the Secretary consider as additional eligible services? In particular, what other services may otherwise have a lack of access for Medicare beneficiaries if an REH does not provide them?

[397] Healthy People 2020 (n.d.) Access to Health Services. *https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services.*

[398] Hempel S., Gibbons M.M., Ulloa J.G., et al. Rural Healthcare Workforce: A Systematic Review [Internet]. Washington (DC): Department of Veterans Affairs (U.S.); 2015 Dec. INTRODUCTION. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK409502/.*

[399] Health Resources and Services Administration. (2021). HRSA Data Warehouse: Designated Health Professional Shortage Areas Statistics. *https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport.*

[400] *Congress.gov.* (2020). H.R.133—Consolidated Appropriations Act, 2021. *https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf.*

3. What, if any, virtual or telehealth services would be appropriate for REHs to provide, and what role could virtual care play in REHs??

4. Should REHs include Opioid Treatment Programs, clinics for buprenorphine induction, or clinics for treating stimulant addiction in their scope of services? Please discuss the barriers that could prevent inclusion of each of these types of services.

5. What, if any, maternal health services would be appropriate for REHs to provide and how can REHs address the maternal health needs in rural communities? What unique challenges or concerns will the providing of care to the maternal health population present for an REH?

Health and Safety Standards, Including Licensure and Conditions of Participation

6. The statute requires that REHs meet the requirements for emergency services (set forth at § 485.618) that apply to CAHs. Which hospital emergency department requirements (set forth at § 482.55) should or should not be mandated for REHs and why or why not? Are there additional health and safety standards that should be considered? What are they, why are they important, and are there data that speak to the need for a particular standard?

7. The REH must meet staff training and certification requirements established by the Secretary. Should these be the same as, or similar to, CAH requirements (*Personnel qualifications,* § 485.604 and *Staffing and staff responsibilities,* § 485.631)? Are there additional or different staff training and certification requirements that should be considered for REHs and why? Are there any staffing concerns that the existing CAH requirements would not address?

8. What additional considerations should CMS be aware of as it evaluates the establishment of CoPs for REHs? Are there data and/or research of which we should particularly be aware?

9. What, if any, lessons have been learned as they relate to rural emergency services during the COVID–19 pandemic that might be pertinent to consider for policy implementation after the Public Health Emergency?

10. Are there state licensure concerns for hospitals and CAHs that wish to become REHs? What issues with respect to existing or potential state licensure requirements should CMS consider when developing the CoPs for this new provider type? What supports and timelines should be in place for States to establish licensing rules?

Health Equity

On January 20 and 21, 2021, President Biden issued three executive orders related to issues of health equity: Executive Order 13985 ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'';[401] Executive Order 13988, ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation'';[402] and Executive Order 13995 ''Ensuring an Equitable Pandemic Response and Recovery''.[403]

Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government'' requires the Federal Government to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality by recognizing and working to redress inequities in its policies and programs that serve as barriers to equal opportunity. In accordance with this Executive order, persons who live in rural areas are identified as belonging to underserved communities that have been adversely affected by inequality.

Executive Order 13988, ''Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation'' requires the Federal Government to prevent and combat discrimination, including when accessing healthcare, on the basis of gender identity or sexual orientation, and to fully enforce Title VII of the Civil Rights Act. This Executive order also requires the Federal Government to fully enforce other laws that prohibit discrimination on the basis of gender identity or sexual orientation, all of which impact all persons, including those in rural communities.

In accordance with Executive Order 13995, ''Ensuring an Equitable Pandemic Response and Recovery,'' the Federal Government must identify and eliminate health and social inequities resulting in disproportionately higher rates of exposure, illness, and death related to COVID–19 and take swift action to prevent and remedy differences in COVID–19 care and outcomes within communities of color and other underserved populations. The Executive order highlights the observed inequities in rural and Tribal communities, territories, and other geographically isolated communities which would have an impact on REHs given the rural communities they will serve.

Consistent with these Executive orders, we are committed to advancing equity for all, including racial and ethnic minorities, members of the lesbian, gay, bisexual, transgendered, and queer/questioning (LGBTQ) community, people with limited English proficiency, people with disabilities, rural populations, and people otherwise adversely affected by persistent poverty or inequality. We are, therefore, asking for public comments on the following health equity focused issues:

11. How can REHs address the social needs arising in rural areas from challenging social determinants of health, which are the conditions in which people are born, live, learn, work, play, worship, and age, and which can have a profound impact on patients' health, ensuring that REHs are held accountable for health equity?

12. With respect to questions 1 through 11 above, are there additional factors we should consider for specific populations including, but not limited to, elderly and pediatric patients; homeless persons; racial, ethnic, sexual, or gender minorities; veterans; and persons with physical, behavioral (for example, mental health conditions and substance use disorders), and/or intellectual and developmental disabilities?

13. How can the CoPs ensure that an REH's executive leadership (that is, its governance, or persons legally responsible for the REH) is fully invested in and held accountable for implementing policies that will reduce health disparities within the facility and the community that it serves? In addition, with regards to governance and leadership, how can the CoPs:

- Encourage a REH's executive leadership to utilize diversity and inclusion strategies to establish a diverse workforce that is reflective of the community that it serves;

[401] The White House. (2021). Briefing Room: Executive Order ON Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[402] The White House. (2021). Briefing Room: Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-preventing-and-combating-discrimination-on-basis-of-gender-identity-or-sexual-orientation/.*

[403] The White House. (2021). Briefing Room: Executive Order on Ensuring an Equitable Pandemic Response and Recovery. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-ensuring-an-equitable-pandemic-response-and-recovery/.*

• Ensure that health equity is embedded into a facility's strategic planning and quality improvement efforts; and

• Ensure that executive leadership is held accountable for reducing health disparities?

14. An important first step in addressing health disparities and improving health outcomes is to begin considering a patient's post-discharge needs and social determinants of health prior to discharge from a facility. How can health equity be advanced through the care planning and discharge planning process? How can the CoPs address the need for REHs to partner with community-based organizations in order to improve a patient's care and outcomes after discharge?

15. In order to ensure that health care workers understand and incorporate health equity concepts as they provide culturally competent care to patients, and in order to mitigate potential implicit and explicit bias that may exist in healthcare, what types of staff training or other efforts would be helpful?

16. Finally, how can the CoPs ensure that providers offer fully accessible services for their patients in terms of physical, communication, and language access with the resources they have available to them?

Collaboration and Care Coordination

17. How can CMS and other Federal agencies best encourage and incentivize collaboration and coordination between an REH and the healthcare providers, entities, or organizations with which an REH routinely works (for example, requirements related to the Emergency Medical Treatment and Active Labor Act, transfer agreements, and participation in EMS protocols), to help the REH successfully fulfill its role in its community? Healthcare providers, entities, and organizations with which an REH might typically work and interact might include, for example, federally qualified health centers, rural health clinics, state and local public health departments, Veterans Administration and Indian Health Service facilities, primary care and oral health providers, transportation, education, employment and housing providers, faith-based entities, and others.

Quality Measurement

The CAA also contains provisions regarding the establishment of quality measurement requirements for REHs, including quality reporting requirements, specification of quality measures, and public availability of quality reporting data. As a result, we are also seeking broad input on the concerns of rural providers that should be taken into consideration by CMS in establishing quality measures and quality reporting requirements for REHs. Specifically, we are asking for stakeholder input on the following questions:

18. What existing quality measures that reflect the care provided in rural emergency department settings can be recommended? What existing quality measures from other quality reporting programs, such as the Hospital Inpatient Quality Reporting and Hospital Outpatient Quality Reporting Programs, are relevant to the services that are likely to be furnished in REHs and should be considered for adoption in the REH context? What measures, specific to REHs, should be developed?

19. Based on experiences in quality reporting by small rural hospitals and CAHs, what barriers and challenges to quality reporting are REHs likely to encounter? What quality reporting strategies should CMS consider to mitigate those barriers?

20. For CAHs, what are the barriers and challenges to electronic submission of quality measures, and will those barriers likely apply to REHs? What similar barriers and challenges could CAHs and REHs experience for chart abstracted measures?

21. What factors should be considered for the baseline measure set and how should CMS assess expanding quality measures for REHs? How could quality measures support survey and certification for REHs?

22. What additional incentives and disincentives for quality reporting unrelated to payment would be appropriate for REHs? Are there limitations or lower limits based on case volume/mix or geographic distance that would be appropriate for CMS to consider when assessing the quality performance of REHs?

23. The inclusion of CAHs within the Overall Hospital Quality Star Ratings provides patients with greater transparency on the performance of CAHs that provide acute inpatient and outpatient care in their area. What factors should CMS consider in determining how to publicly report REH quality measure data?

Payment Provisions

We are also soliciting stakeholder input regarding the payment provisions established for rural emergency hospitals and that will go into effect for items and services furnished on or after January 1, 2023. Specifically, we are asking for stakeholder input on the following items:

24. Under the law, only existing critical access hospital or subsection (d) hospitals with not more than 50 beds that are located in a rural area are eligible to convert to an REH. While REHs will receive the applicable OPPS rate that would otherwise apply under section 1833(t)(1) of the Act and with an increase of 5 percent under section 1834(x)(1) of the Act as well as an additional facility payment to be made on a monthly basis under section 1834(x)(2) of the Act, we note that rural sole community hospitals (SCHs) currently receive an additional 7.1 percent payment for all services paid through the OPPS. We are seeking comment on the likelihood of rural SCHs deciding to seek to become REHs.

25. In order to calculate the additional annual facility payment for rural emergency hospitals required by section 1834(x)(2) of the Act, CMS will need to compare all CY 2019 payments to CAHs with an estimate of the total amount of payment that would have been made to CAHs in CY 2019 if CAHs were paid through the inpatient, outpatient, and skilled nursing facility prospective payment systems, rather than receiving Medicare payment at 101 percent of the reasonable costs of these services. Are there any claims or other payment reporting issues that CMS should consider when calculating the hypothetical estimated payment under the prospective payment systems for services furnished by CAHs in CY 2019?

26. We also are seeking comment on whether the claims forms used by CAHs to report inpatient hospital services, outpatient hospital services, and skilled nursing services contain all of the necessary information in order that the claims could be processed by the applicable CMS prospective payment systems. We are seeking this information because section 1834(x)(2)(C) of the Act requires as a part of the calculation to determine the additional facility payment for CY 2023 for CMS to estimate what CAHs would have received for payment of inpatient hospital services, outpatient hospital services, and skilled nursing facility services if those services were paid through their respective prospective payment systems. We want to know what barriers, if any, we may face when attempting to use CAH claims to perform this calculation. If the CAH claims are missing information that would be required to process the claims through a prospective payment system, what challenges could CAHs face in collecting the missing information and submitting it to CMS for processing?

27. The statute requires that a facility seeking to enroll as an REH must provide information regarding how the facility intends to use the additional facility payment provided under section 1834(x)(2) of the Act, including a detailed description of the services that the additional facility payment would be supporting, such as furnishing of telehealth and ambulance services, including operating the facility and maintaining the emergency department to provide covered services. What challenges will providers face to maintain and submit what will likely be similar detailed information about how their facility has spent the additional facility payment for rural emergency hospitals as required by section 1834(x)(2)(D) of the Act? What assistance or guidance should HHS consider providing to facilities to meet this reporting requirement?

Enrollment Process

28. The statute requires that an eligible facility must submit an application to enroll as an REH in a form determined by the Secretary. In accordance with the requirements of the CAA, the application for enrollment must include an action plan for initiating REH services, including a detailed transition plan that lists the specific services that the facility will retain, modify, add and discontinue. What suggestions do facilities who are considering enrolling as REHs want us to take into account in developing the enrollment requirements?

29. What considerations should be taken into account regarding the steps and timing for conversion to an REH?

CMS appreciates comments and feedback as we work towards developing new health and safety standards for REHs and establishing payment rules to implement the statutory payment methodology. In accordance with the statute, CMS intends to engage in rulemaking to implement these provisions. We intend to consider the comments received in response to this request for information to inform the development of a proposed rule that will solicit comments on the implementation of this new provider type. In accordance with the statute, we will propose and finalize provisions establishing and governing REHs in time for the statutorily required effective date of January 1, 2023.

XVIII. Radiation Oncology Model

A. Introduction

On September 29, 2020, the Centers for Medicare & Medicaid Services (CMS) published in the **Federal Register** the final rule entitled ''Specialty Care Models to Improve Quality of Care and Reduce Expenditures,'' hereafter referred to as the Specialty Care Models Rule (85 FR 61114) and codified policies at 42 CFR part 512. The Radiation Oncology (RO) Model is designed to test whether prospective episode-based payments for radiotherapy (RT) services (also referred to as radiation therapy services) will reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. As radiation oncology is highly technical and furnished in well-defined episodes, and because patient comorbidities generally do not influence treatment delivery decisions, we believe that radiation oncology is well-suited for testing a prospective episode payment model. Under the RO Model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for service (FFS) beneficiaries diagnosed with certain cancer types. The RO Model will include 30 percent of all eligible RO episodes (these occur in 204 eligible Core-Based Statistical Areas (CBSAs) in 48 states and the District of Columbia). We finalized that the base payment amounts for RT services included in the RO Model would be the same for hospital outpatient departments (HOPDs) and freestanding radiation therapy centers. We finalized that the model performance period [404] for the RO Model would be five performance years (PYs), beginning January 1, 2021, and ending December 31, 2025, with final data submission of clinical data elements and quality measures in 2026 to account for episodes ending in 2025.

To ensure that participation in the RO Model during the public health emergency (PHE) for the Coronavirus disease 2019 (COVID–19) pandemic did not further strain RO participants' capacity, CMS revised the RO Model's model performance period to begin on July 1, 2021, and end December 31, 2025, in the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs final rule with comment period (CMS–1736–IFC) (85 FR 85866) (hereinafter referred to as ''CY 2021 OPPS/ASC final rule''). In the CY 2021 OPPS/ASC final rule, we changed the duration of the model performance period from 5 years to 4.5 years, changed the timelines for the submission of clinical data elements, quality measures and Certified Electronic Health Record Technology (CEHRT) requirements, and modified the eligibility dates of the RO Model as an Advanced Alternative Payment Model (APM) and Merit-based Incentive Payment System (MIPS) APM (85 FR 85866).

Section 133 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260), enacted on December 27, 2020, included a provision that prohibits implementation of the RO Model before January 1, 2022. This Congressional action supersedes the RO Model delayed start date established in the CY 2021 OPPS/ASC final rule. In this proposed rule, we are proposing provisions related to the additional delayed implementation due to the CAA, 2021, as well as modifications to certain RO Model policies not related to the delay. We are proposing to modify §§ 512.205, 512.210, 512.217, 512.220, 512.230, 512.240, 512.245, 512.250, 512.255, 512.275, 512.280, and 512.285 and add §§ 512.292 and 512.294.

B. Background

We are committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs. Accordingly, as part of that effort, we have in recent years undertaken a number of initiatives to improve cancer treatment, most notably with our Oncology Care Model (OCM). We believe that a model in radiation oncology will further these efforts to improve cancer care for Medicare beneficiaries and reduce Medicare expenditures.

Radiotherapy is a common treatment, received by nearly two thirds of all patients undergoing cancer treatment, and it is typically furnished by a radiation oncologist.[405] [406] As described in the 2017 REPORT TO CONGRESS: Episodic Alternative Payment Model for Radiation Therapy Services and the Specialty Care Models (Proposed Rule), CMS–5527–P (84 FR 34490), because there are differences in the underlying methodologies used for rate setting in the OPPS and Physician Fee Schedule (PFS), there often are differences in the payment rate for the same RT service depending on whether the service is furnished in a freestanding radiation

[404] CMS has made a stylistic change to this term. CMS changed ''Model performance period'' to ''model performance period'' to be consistent with other CMMI Models.

[405] Physician Characteristics and Distribution in the U.5., 2010 Edition, 2004 IMV Medical Information Division, 2003 SROA Benchmarking Survey.

[406] 2012/13 Radiation Therapy Benchmark Report, IMV Medical Information Division, Inc. (2013).

therapy center paid under the PFS, or an HOPD paid under the OPPS. This is called the site-of-service payment differential, and stakeholders from freestanding radiation therapy centers have asserted that such differentials between HOPDs and freestanding radiation therapy centers are unwarranted because the actual treatment and care received by patients for a given modality is the same in each setting.

For these reasons, the RO Model is designed to test whether making site-neutral, prospective episode-based payments to HOPDs, physician group practices (PGPs), and freestanding radiation therapy centers for RT episodes of care preserves or enhances the quality of care furnished to Medicare beneficiaries while reducing or maintaining Medicare program spending.

C. RO Model Proposed Regulations

1. Proposed Model Performance Period

In the Specialty Care Models Rule, we specified at § 512.205 that the model performance period would last five performance years, beginning January 1, 2021, and ending December 31, 2025 (85 FR 61367). We finalized that each PY is the 12-month period beginning on January 1 and ending on December 31 of each CY during the model performance period, and no new RO episodes may begin after October 3, 2025, in order for all RO episodes to end by December 31, 2025.

In the CY 2021 OPPS/ASC final rule, we amended the definition of model performance period, specifying that it would begin July 1, 2021 and end on December 31, 2025, and we amended the definition of PY to mean the 6-month period beginning on July 1, 2021, and ending on December 31, 2021, and the 12-month period beginning on January 1 and ending on December 31 of each subsequent year (2022 through 2025) during the model performance period.

Section 133 of the CAA 2021 prohibits implementation of the RO Model prior to January 1, 2022. We are proposing to begin the RO Model as soon as we are permitted to do so by law, on January 1, 2022, as we continue to believe that a prospective episode payment model is needed and well suited to be tested in the radiation oncology space. We are proposing to modify the model performance period to begin on January 1, 2022, and end December 31, 2026 as described in detail in the proposed definitions in section XVIII.C.2. No new RO episodes may begin after October 3, 2026, in order for all RO episodes to end by December 31, 2026. We are also proposing that each PY will be a 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period, unless the initial model performance period starts mid-year, in which case PY1 will begin on that date and end on December 31 of that year.

We invite public comments on these proposals related to the dates associated with the model performance period.

2. Proposed Definitions

We codified at § 512.205 definitions for the RO Model. We are proposing to modify some of these definitions in this proposed rule and add a definition for baseline period, as described in more detail later in this section of the preamble. We are also proposing to add a definition for ''EUC'' (extreme and uncontrollable circumstances) to correspond with the proposed EUC policy described in more detail in section XVIII.C.10 of this proposed rule. To describe how changes in CMS Certification Numbers (CCNs) and Tax Identification Numbers (TINs) are treated under the RO Model, which is described in more detail in section XVIII.C.5.g of this proposed rule, we are also proposing to add definitions for ''legacy CCN'' and ''legacy TIN''. And, to clarify how RO Model requirements align with the Quality Payment Program (QPP), we are proposing to add definitions for ''Track One'' and ''Track Two'' as described in section XVIII.C.7 of this proposed rule.

We are proposing to add a definition for ''baseline period'', specifying which episodes (dependent on the model performance period) are used in the pricing methodology. We propose to define ''baseline period'' to mean the three calendar year (CY) period that begins on January 1 no fewer than 5 years but no more than 6 years prior to the start of the model performance period during which episodes must initiate in order to be used in the calculation of the national base rates, participant-specific professional and technical historical experience adjustments for the model performance period, and the participant-specific professional and technical case mix adjustments for PY1. The baseline period would be January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in CY 2022, in which case the baseline period would be adjusted according to the new model performance period (that is, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

We propose to modify the definition of the ''model performance period'' to mean the five PYs during which RO episodes must initiate and terminate. The model performance period would begin on January 1, 2022 and end on December 31, 2026, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1.

We propose to modify the definition of ''PY'' (performance year) to mean each 12-month period beginning on January 1 and ending on December 31 during the model performance period, unless the model performance period begins on a date other than January 1, in which case, the first performance year (PY1) would begin on that date and end on December 31 of the same year.

We propose to modify the definition of ''stop-loss reconciliation amount'' to mean the amount set forth in § 512.285(f) owed by CMS for the loss incurred under the Model to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

We invite public comments on these proposed definitions.

3. Proposed RO Model Participant Exclusions

At § 512.210(b), we exclude from the RO Model any PGP, freestanding radiation therapy center, or HOPD that furnishes RT only in Maryland; furnishes RT only in Vermont; furnishes RT only in United States (U.S.) Territories; is classified as an ambulatory surgical center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or participates in or is identified by CMS as eligible to participate in the Pennsylvania Rural Health Model (PARHM).

a. Pennsylvania Rural Health Model (PARHM)

We are proposing to modify § 512.210(b)(5) to exclude from the RO Model only the HOPDs that are participating in PARHM, rather than excluding both HOPDs that are participating in PARHM and those that have been identified by CMS as eligible to participate in PARHM. We continue to believe that HOPDs that are participating in PARHM should be excluded from the RO Model because these hospitals receive global budgets,

and these global budgets would include payments for RT services and as such would overlap with the RO Model payment. In the Specialty Care Models final rule, we also excluded HOPDs that are eligible to participate in the PARHM from the RO Model on the grounds that additional hospitals and CAHs may join PARHM in the future or may be included in the evaluation comparison group for that model (see 85 FR 61144).

However, after further consideration, we believe that including in the RO Model those HOPDs that have been identified as eligible to participate in PARHM, but that are not actually participating in PARHM because they are not currently a party to a PARHM participation agreement with CMS, would not affect the PARHM evaluation. First, such HOPDs do not receive global budgets under PARHM, so including these hospitals in the RO Model would not result in an overlap between PARHM payments and RO Model payments. Second, while we initially explored the potential for HOPDs that are eligible to participate in PARHM being included in that model's evaluation comparison group, we now expect that the PARHM comparison group will consist only of hospitals located outside of Pennsylvania because of selection constraints. Thus, it is now our expectation that HOPDs that have been identified as eligible to participate in PARHM—all of which are located within the Commonwealth of Pennsylvania—would not be selected for the comparison group for the PARHM evaluation. Accordingly, we do not expect that including in the RO Model those HOPDs that have been identified as eligible to participate, but not actually participating in, PARHM would affect the ability to detect the impact of PARHM on the cost and quality of care.

In addition, while it remains the case that hospitals and CAHs may join PARHM on an ongoing basis, hospitals and CAHs generally join PARHM at the start of a given CY. Because the RO Model's PYs would align with CYs, we have concluded it would be possible to update the RO Model exclusions for a given PY if an HOPD leaves or joins PARHM. For instance, if a rural hospital identified as eligible to participate in PARHM later initiates its participation in PARHM by signing a PARHM participation agreement with CMS, then the HOPDs participating in PARHM as part of that participating rural hospital would be excluded from participation in the RO Model as of the start of the next CY quarter that follows the date that the HOPD begins participating in PARHM. Similarly, if an HOPD no longer participates in PARHM as part of a participating rural hospital, and the HOPD otherwise meets the definition of an RO participant, then the HOPD would be required to participate in the RO Model as of the start of the next CY quarter.

We would continue to use the list on the PARHM website at *https://innovation.cms.gov/initiatives/pa-rural-health-model/*, which is updated quarterly, to identify the hospitals that are participating in PARHM, and therefore identify the specific HOPDs excluded from participation in the RO Model. We therefore are proposing that HOPDs that are identified as eligible to participate in PARHM, but that are not current PARHM participants, should be included in the RO Model if they are located in a CBSA selected for participation in the RO Model and that this exclusion of HOPDs associated with hospitals that participate in PARHM from the RO Model would apply only during the period of such participation.

We invite public comments on the inclusion of HOPDs eligible to participate in PARHM, but that are not current PARHM participants in the RO Model.

b. Community Health Access and Rural Transformation Model

We are also proposing to modify the exclusions from the RO Model at § 512.210(b)(6) so that the HOPD of any participating hospital in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model is excluded from the RO Model. Specifically, for any CHART Community Transformation Track performance period during which a hospital is participating in the CHART Model, the HOPD would be excluded from the RO Model. We are proposing to exclude these ''CHART HOPDs'' because these hospitals will receive prospective capitated payments, including HOPD-based RT services, that are not retrospectively reconciled based on experience during the CHART performance year, rather future payments are adjusted based on changes in population and proportion of services that participating HOPDs provide. We are proposing to exclude CHART HOPDs to avoid double payment for the same services. The participating hospitals will be listed and updated on the CHART Model website at *https://innovation.cms.gov/innovation-models/chart-model*. For the CHART ACO Transformation Track, we will follow the same policy for overlap between the RO Model and the Medicare Shared Savings Program ACOs, which was finalized at 85 FR 61260.

We invite public comments on the exclusion of HOPDs the HOPD of any participating hospital in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model from the RO Model.

c. Low Volume Opt-Out

We codified at § 512.210(c) that a PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt out of the RO Model for a given PY if it has fewer than 20 episodes of RT services across all CBSAs selected for participation in the most recent year with claims data available prior to the applicable PY. In the CY 2021 OPPS/ASC final rule (85 FR 86261), we amended this policy at § 512.210(c) to clarify the type of episodes used to determine eligibility for the low volume opt-out in each performance year, where episodes, as defined at § 512.205, are used to determine eligibility in PY1 and PY2 and RO episodes, as defined at § 512.205 and described at § 512.245(a), are used to determine eligibility in PY4 and PY5, and both episodes and RO episodes are used to determine eligibility in PY3. Specifically, for PY3, eligibility for the low volume opt-out is determined by counting episodes from January 1, 2021 through June 30, 2021 and RO episodes from July 1, 2021 through December 31, 2021.

Because section 133 of the CAA 2021 prohibits implementation of the RO Model prior to January 1, 2022, in this proposed rule, we are again clarifying the dates of the data used to determine eligibility for the low volume opt-out. A PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt-out of the RO Model for a given PY if it has fewer than 20 episodes or RO episodes, as applicable, depending on the PY, across all CBSAs selected for participation in the most recent year with claims data available, which is 2 years prior to the applicable PY. At least 30 days prior to the start of each PY, CMS will notify RO participants eligible for the low volume opt-out for the upcoming PY. If the RO participant wishes to opt out, it must attest that it intends to do so prior to the start of the upcoming PY. We are further clarifying that episodes furnished prior to the start of the model performance period in CBSAs selected for participation will be used to determine the eligibility of the low volume opt-out for PY1 and PY2. If PY1 begins on January 1, RO episodes will be used to determine the eligibility of the low volume opt-out for PY3. If

PY1 begins on any date other than January 1, both RO episodes of PY1 and episodes occurring in the CY of PY1 (but occurring prior to the start of PY1 in that year) in CBSAs selected for participation will be used to determine the eligibility of the low volume opt-out for PY3. RO episodes of PY2 and PY3 will be used to determine the eligibility of the low volume opt-out for PY4 through PY5, respectively.

We are proposing to codify at § 512.210(c)(7) that during the model performance period, an entity would not be eligible for the low volume opt-out if its legacy TIN or legacy CCN was used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the 2 years prior to the applicable PY across all CBSAs selected for participation across all CBSAs selected for participation.

If finalized as proposed, CMS would include episodes and RO episodes, as applicable, associated with the RO participant's current CCN or TIN and episodes and RO episodes, as applicable, attributed to the RO participant's legacy CCN(s) or legacy TIN(s). We propose that a legacy CCN means a CCN that an RO participant that is a hospital outpatient department, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services. We propose that a legacy TIN means a TIN that an RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.

We are proposing this change to remove any incentive for RO participants to change their TIN or CCN in an effort to become eligible for the low volume opt-out.

We invite public comments on the proposed definitions of legacy TIN and legacy CCN, as well as the proposal for how to address low volume opt-out eligibility in the case of an entity that has a change in TIN or CCN.

4. Certain Changes to RO Model Episodes

a. Criteria for Determining Included Cancer Types

The criteria for cancer types to be included in the RO Model are set forth at § 512.230(a). To be included in the RO Model, a cancer type must be commonly treated with radiation and associated with current International Classification of Diseases (ICD)–10 codes that have demonstrated pricing stability. We also established the criteria for removal of cancer types from the RO Model are set forth at § 512.230(b). CMS will remove a cancer type from the RO Model if it determines that RT is no longer appropriate to treat that cancer type per nationally recognized, evidence-based clinical treatment guidelines; CMS discovers a >10 percent error in established national base rates; or the Secretary determines that the cancer type is not suitable for inclusion in the RO Model.

Upon further review, we believe that reorganization of § 512.230(a) and (b) would improve the clarity and internal consistency of the regulatory text. We are therefore proposing to amend § 512.230(a) and (b) such that to be included in the RO Model, a cancer type must be commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines; associated with current ICD–10 codes that have demonstrated pricing stability, which is determined by analyzing the interquartile ranges of the episode prices across cancer types as described in the Specialty Care Models final rule at 85 FR 61155; and the Secretary must not have determined that the cancer type is not suitable for inclusion in the RO Model. We propose that CMS will remove from the RO Model a cancer type that does not meet all three of these criteria or for which CMS discovers a >10 percent error in established national base rates.

We invite public comments on the reorganization of § 512.230(a) and (b).

b. Removal of Liver Cancer From Included Cancer Types

We finalized 16 cancer types (Anal Cancer, Bladder Cancer, Bone Metastases, Brain Metastases, Breast Cancer, Cervical Cancer, Central Nervous System (CNS) Tumors, Colorectal Cancer, Head and Neck Cancer, Liver Cancer, Lung Cancer, Lymphoma, Pancreatic Cancer, Prostate Cancer, Upper Gastrointestinal (GI) Cancer, and Uterine Cancer) for inclusion in the RO Model because they meet the criteria set forth in § 512.230(a) (85 FR 61157). These cancers are commonly treated with RT and are associated with current ICD–10 codes that have demonstrated pricing stability. They can be accurately priced for prospective episode payments in that episode prices across these included diagnosis codes the RO Model have been stable.

The treatment of liver cancer with RT services continues to develop, with limited guidance for first-line use of radiotherapy.[407] While RT may represent a promising treatment for certain types of liver cancers, there are few prospective, randomized controlled trials.[408] Some guidelines do not include radiotherapy as a first-line therapy for the treatment of the most common type of liver cancer, hepatocellular carcinoma.[409] After continued conversations with radiation oncologists consulting on the RO Model and additional reviews of the latest literature, we now believe that the inclusion of liver cancer does not meet the inclusion criteria at § 512.230(a)(1) because liver cancer is not commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines.

We believe that liver cancer meets the current criteria for exclusion and that it would meet the criteria for exclusion under our proposal to reorganize the regulatory language in § 512.230(a) and (b) as described earlier in more detail. Therefore, if the reorganization is finalized as proposed, or if the current regulatory text is not changed, we will remove liver cancer from the RO Model as an included cancer type. We will remove the liver cancer ICD–10 diagnosis code(s) from the list on the RO Model website no later than 30 days prior to the start of the model performance period in accordance with § 512.230(c).

c. Proposal To Remove Brachytherapy From Included RT Services

We codified at § 512.240 the modalities that are included under the RO Model: 3-dimensional conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), proton beam therapy (PBT), image-guided radiation therapy (IGRT), and brachytherapy. We finalized the inclusion of all of these modalities because they are commonly used to treat

[407] Marrero, J.A., Kulik, L.M., Sirlin, C.B., Zhu, A.X., Finn, R.S., Abecassis, M.M., Roberts, L.R., & Heimbach, J.K. (2018). Diagnosis, Staging, and Management of Hepatocellular Carcinoma: 2018 Practice Guidance by the American Association for the Study of Liver Diseases. *Hepatology (Baltimore, Md.), 68*(2), 723–750. *https://doi.org/10.1002/hep.29913.*

[408] Chen C.P. (2019). Role of Radiotherapy in the Treatment of Hepatocellular Carcinoma. *Journal of clinical and translational hepatology, 7*(2), 183–190. *https://doi.org/10.14218/JCTH.2018.00060.*

[409] Marrero, J.A., Kulik, L.M., Sirlin, C.B., Zhu, A.X., Finn, R.S., Abecassis, M.M., Roberts, L.R., & Heimbach, J.K. (2018). Diagnosis, Staging, and Management of Hepatocellular Carcinoma: 2018 Practice Guidance by the American Association for the Study of Liver Diseases. *Hepatology (Baltimore, Md.), 68*(2), 723–750. *https://doi.org/10.1002/hep.29913.*

the cancer types included in the RO Model and because including these modalities would allow us to test a modality-agnostic approach.

In response to the publication of the Specialty Care Models proposed rule and final rule, we received stakeholder feedback encouraging CMS to reconsider how multimodality episodes—which are episodes involving two or more types of RT treatment—are handled in the RO Model, especially in the cases of cervical cancer and prostate cancer, where standard clinical practice is concordant treatment with external beam radiation therapy (EBRT) and brachytherapy. Stakeholders expressed concern that the RO episode-based payment does not account for multimodality care. Stakeholders were particularly concerned about cases where the RO participant furnishing the external beam radiation therapy is different from the RO participant providing brachytherapy. Stakeholders suggested creating a separate bundled payment for brachytherapy or removing it from the RO Model. We have also heard continued concern from some stakeholders about the inclusion of the brachytherapy sources, particularly fast-acting radioisotopes, in the bundled payments, because they are more like medical devices used in conjunction with medical procedures than other modalities. Brachytherapy sources are also typically paid for separately.

Some stakeholders suggested that inclusion of brachytherapy in the bundled payments could lead to reduced utilization of brachytherapy in situations where a combination of brachytherapy and EBRT is clinically indicated (particularly for cervical and prostate cancers). Stakeholders expressed concern that in the case of multimodality treatment including brachytherapy, there may be a disincentive to refer patients to other radiation oncologists for treatment when the RO participant cannot deliver brachytherapy services themselves.

CMS seeks to neither incentivize nor discourage the use of one modality over another, but rather to encourage providers to choose RT services that are the most clinically appropriate for beneficiaries under their care. The exclusion of a modality from the RO Model is not meant to imply anything about the value of such modality. Published clinical evidence suggests brachytherapy is a high-value RT service, which could warrant its inclusion in the RO Model. However, we acknowledge the concerns stakeholders have about possible unintended consequences for beneficiaries' access to care.

We are proposing to amend § 512.240 to remove brachytherapy as an included modality in the RO Model. If finalized as proposed, we would continue to monitor utilization of brachytherapy, both as a single modality and multimodality among RO participants compared to non-participants, and consider whether there is opportunity to adjust pricing for multimodality episodes, without disrupting the RO Model design, and potentially add brachytherapy to the RO Model in the future. We would also make conforming edits to the list of included RT services previously set forth in the Specialty Care Models Rule at 85 FR 61166 to account for the proposed removal of brachytherapy. The proposed list of included RT services as identified by HCPCS codes are in Table 56 of this proposed rule.

We invite public comments on the removal of brachytherapy.

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TABLE 56: List of RO Model Bundle HCPCS

HCPCS	HCPCS Description	Category
77014	Computed tomography guidance for placement of	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77021	Magnetic resonance guidance for needle placem	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77261	Radiation therapy planning	Treatment Planning
77262	Radiation therapy planning	Treatment Planning
77263	Radiation therapy planning	Treatment Planning
77280	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77285	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77290	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77293	Respirator motion mgmt simul	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77295	3-d radiotherapy plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77299	Radiation therapy planning	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77300	Radiation therapy dose plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77301	Radiotherapy dose plan imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77306	Telethx isodose plan simple	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77307	Telethx isodose plan cplx	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77321	Special teletx port plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77331	Special radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77332	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77333	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77334	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77336	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77338	Design mlc device for imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77370	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77371	Srs multisource	Radiation Treatment Delivery
77372	Srs linear based	Radiation Treatment Delivery
77373	Sbrt delivery	Radiation Treatment Delivery
77385	Ntsty modul rad tx dlvr smpl	Radiation Treatment Delivery
77386	Ntsty modul rad tx dlvr cplx	Radiation Treatment Delivery

77399	External radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77402	Radiation treatment delivery	Radiation Treatment Delivery
77407	Radiation treatment delivery	Radiation Treatment Delivery
77412	Radiation treatment delivery	Radiation Treatment Delivery
77417	Radiology port images(s)	Radiation Treatment Delivery (Guidance)
77427	Radiation tx management x5	Treatment Management
77431	Radiation therapy management	Treatment Management
77432	Stereotactic radiation trmt	Treatment Management
77435	Sbrt management	Treatment Management
77470	Special radiation treatment	Treatment Management
77499	Radiation therapy management	Treatment Management
77520	Proton trmt simple w/o comp	Radiation Treatment Delivery
77522	Proton trmt simple w/comp	Radiation Treatment Delivery
77523	Proton trmt intermediate	Radiation Treatment Delivery
77525	Proton treatment complex	Radiation Treatment Delivery
G0339	Robot lin-radsurg com, first	Radiation Treatment Delivery
G0340	Robt lin-radsurg fractx 2-5	Radiation Treatment Delivery
G6001	Echo guidance radiotherapy	Radiation Treatment Delivery (Guidance)
G6002	Stereoscopic x-ray guidance	Radiation Treatment Delivery (Guidance)
G6003	Radiation treatment delivery	Radiation Treatment Delivery
G6004	Radiation treatment delivery	Radiation Treatment Delivery
G6005	Radiation treatment delivery	Radiation Treatment Delivery
G6006	Radiation treatment delivery	Radiation Treatment Delivery
G6007	Radiation treatment delivery	Radiation Treatment Delivery
G6008	Radiation treatment delivery	Radiation Treatment Delivery
G6009	Radiation treatment delivery	Radiation Treatment Delivery
G6010	Radiation treatment delivery	Radiation Treatment Delivery
G6011	Radiation treatment delivery	Radiation Treatment Delivery
G6012	Radiation treatment delivery	Radiation Treatment Delivery
G6013	Radiation treatment delivery	Radiation Treatment Delivery
G6014	Radiation treatment delivery	Radiation Treatment Delivery
G6015	Radiation tx delivery imrt	Radiation Treatment Delivery
G6016	Delivery comp imrt	Radiation Treatment Delivery
G6017	Intrafraction track motion	Radiation Treatment Delivery (Guidance)

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Our proposal to remove brachytherapy from the RO Model, if finalized, would render our waiver of section 1833(t)(2)(H) of the Act (as discussed in the Specialty Care Models Rule at 85 CFR 61242 and codified at § 512.280(f)(4) moot, and therefore we are proposing to withdraw this waiver if our proposal to remove brachytherapy is finalized as proposed. We finalized this waiver under the authority of section 1115A(d)(1) of the Act, because it was necessary for the purposes of testing the RO Model when we were including brachytherapy as part of the RO Model. Because we are proposing to remove brachytherapy from the RO Model, we believe that the waiver under section 1833(t)(2)(H) of the Act would no longer be necessary solely for the purposes of testing the RO Model and therefore are proposing to withdraw this waiver.

We invite public comments on the removal of the 1833(t)(2)(H) waiver.

If we remove brachytherapy from the RO Model, we are requesting information on how payments for multi-modality care might be handled in the future. For example, we request information on how RO participants should be paid under the RO Model in cases where brachytherapy is furnished in conjunction with one or more other modalities during an RO episode. CMS does not intend to respond to these comments in the CY 2022 OPPS/ASC final rule; instead, we intend to use these comments to inform potential changes to the RO Model that could be proposed in future notice and comment rulemaking.

d. Exclusion of Intraoperative Radiotherapy (IORT)

We finalized that Intraoperative Radiotherapy (IORT)—a technique that involves precise delivery of a large dose of ionizing radiation to the tumor or tumor bed during surgery—would not be included in the RO Model in the Specialty Care Models Rule (85 FR 61175). We have received comments from stakeholders requesting that we re-evaluate this decision and include IORT in the RO Model for certain cancer types, particularly early stage breast cancer.

At this time, episode payment rates are modality-agnostic. They include all Medicare FFS claims paid during the baseline period as well as claims that are included under an episode where the initial treatment planning service occurred during the baseline period so long as the RT service furnished is not of a modality excluded from the RO Model. We do not have separate national base rates per included cancer type based on a specific modality. Given that the evidence base for IORT is limited to certain cancer types, it does not meet the qualifications for inclusion in this Model. As we have reconsidered IORT's inclusion, we also note that it is a modality that is not site neutral, meaning that the TC of IORT is primarily delivered in HOPDs (during surgery) instead of freestanding radiation therapy centers. One of the primary goals of the RO Model is to test site neutral payments, where care delivered in HOPDs or freestanding radiation therapy centers are paid the same bundled payment. Given that this modality is only provided in one of those locations, it is not site neutral, and therefore does not meet the goals of the RO Model. Modalities that are not included in the RO Model, including IORT, would continue to be paid under Medicare FFS.

We are soliciting comments on whether and how we might include IORT in our pricing methodology in future years of the RO Model, for example whether CMS should include cancer-specific modalities in the RO Model. CMS does not intend to respond to these comments in this CY 2022 OPPS/ASC final rule. We intend to use these comments to inform potential changes to the RO Model that could be proposed in future notice and comment rulemaking.

5. Pricing Methodology

a. Assignment of Cancer Types to an Episode

We finalized at 85 FR 61179 our process for assigning a cancer type to an episode as follows: First, we identify ICD–10 diagnosis codes during an episode from: (1) Medicare PFS claims for evaluation and management (E&M) services with an included cancer diagnosis code with a date of service during the 30 days before the episode start date, on the episode start date, or during the 29 days after the episode start date; and (2) Medicare PFS claims for treatment planning and delivery services with an included cancer diagnosis code (See Table 57), or Medicare OPPS claims for treatment delivery services with an included cancer diagnosis code on the claim header, with a date of service on the episode start date or during the 29 days after the episode start date. The cancer diagnosis code from OPPS claims must be the principal diagnosis to count toward cancer type assignment, and treatment delivery services that concern image guidance do not count toward cancer type assignment as we determined that image guidance was not an important indicator of cancer type. Then, we analyze and count these ICD–10 diagnosis codes across the claim lines to determine the episode's cancer type assignment according to the algorithm described in (1) through (3):

(1) If two or more claim lines fall within brain metastases or bone metastases or secondary malignancies (per the mapping of ICD–10 diagnosis code to cancer type described in Table 57 of Identified Cancer Types and Corresponding ICD–10 Codes), we set the episode cancer type to the type (either brain metastases or bone metastases) with the highest count. If the count is tied, we assign the episode in the following order of precedence: Brain metastases; bone metastases; other secondary malignancies.

(2) If there are fewer than two claim lines for brain metastases, bone metastases or other secondary malignancies, we assign the episode the cancer type with the highest claim line count among all other cancer types. We exclude the episode if the cancer type with the highest claims line count among other cancer types is not an included cancer type.

(3) If there are no claim lines with a cancer diagnosis meeting the previously discussed criteria, then no cancer type is assigned to that episode and therefore, that episode is excluded from the national base rate calculations.

Since the publication of the Specialty Care Models Rule, a stakeholder has asked for clarification on how to identify when there are fewer than two claim lines for brain metastases, bone metastases or other secondary malignancies. In response to the stakeholder's request, in this proposed rule, we would like to clarify paragraph (2). Specifically, if there are not at least two claim lines for brain metastases or at least two claim lines for bone metastases or at least two claim lines for any other secondary malignancy, then we assign the episode the cancer type with the highest line count among all other cancer types. For example, one bone metastases claim line and one secondary metastases claim line would not qualify as two or more claim lines that fall within brain metastases or bone metastases or secondary malignancies. Instead, the episode would be assigned whatever cancer type had the highest line count among all other cancers.

We would also like to clarify that we use a broad list of cancer diagnoses (those included in the RO Model and those not included) to assign cancer type to episodes in the baseline period. This broad list of cancer diagnoses will be posted on the RO Model website at *https://innovation.cms.gov/innovation-models/radiation-oncology-model*. We identify ICD–10 diagnosis codes for cancer during an episode from E&M services, and treatment planning and delivery services that have a cancer diagnosis code from that broad cancer diagnosis list. We assign a cancer type to the episode as described in the Specialty Care Models Rule at 85 FR 61179. We then exclude those episodes that are not assigned an included cancer type. We do not exclude claims of excluded cancer types prior to episode construction, as this could lead to an episode being included in the RO Model where most of the RT services were related to treating an excluded cancer type.

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TABLE 57: Identified Cancer Types and Corresponding ICD-10 Codes

Cancer Type	ICD-10 Codes
Anal Cancer	C21.xx
Bladder Cancer	C67.xx
Bone Metastases	C79.51
Brain Metastases	C79.3x
Breast Cancer	C50.xx, D05.xx
Cervical Cancer	C53.xx
CNS Tumors	C70.xx, C71.xx, C72.xx
Colorectal Cancer	C18.xx, C19.xx, C20.xx
Head and Neck Cancer	C00.xx, C01.xx, C02.xx, C03.xx, C04.xx, C05.xx, C06.xx, C07.xx, C08.xx, C09.xx, C10.xx, C11.xx, C12.xx, C13.xx, C14.xx, C30.xx, C31.xx, C32.xx, C76.0x
Lung Cancer	C33.xx, C34.xx, C39.xx, C45.xx
Lymphoma	C81.xx, C82.xx, C83.xx, C84.xx, C85.xx, C86.xx, C88.xx, C91.4x
Pancreatic Cancer	C25.xx
Prostate Cancer	C61.xx
Upper GI Cancer	C15.xx, C16.xx, C17.xx
Uterine Cancer	C54.xx, C55.xx

b. Proposal To Construct Episodes Using Medicare FFS Claims and Calculation of Episode Payment

We finalized at 85 FR 61181 that we construct episodes based on dates of service for Medicare FFS claims paid during the baseline period (CYs 2016 through 2018) as well as claims that are included under an episode where the initial treatment planning service occurred during the baseline period. In the construction of episodes, we also weigh the most recent observations more heavily than those that occurred in earlier years, weighting episodes that initiated in 2016 at 20 percent, episodes that initiated in 2017 at 30 percent, and episodes that initiated in 2018 at 50 percent.

We are proposing to update how we describe this approach. Although we are removing references to specific CYs from the definition of baseline period, we still construct episodes based on dates of service for Medicare FFS claims paid during the baseline period as well as claims that are included under an episode where the initial treatment planning service occurred during the baseline period. Furthermore, although we are removing references to specific CYs, we will continue to weigh the most recent observations more heavily than those that occurred in earlier years, as previously finalized. We would continue to weigh episodes that initiated in the first year of the baseline period at 20 percent, episodes that initiated in second year of the baseline period at 30 percent, and episodes that initiated in the third year of the baseline period at 50 percent.

We invite public comment on this proposal to weigh the most recent episodes more heavily than those that occurred in earlier years in the baseline period.

We codified at § 512.255(c)(13) that for sequestration, we deduct 2 percent from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rate. At times, the requirements for sequestrations are modified by legislation or regulation. For example, section 3709(a) of division A of the Coronavirus Aid, Relief and Economic Security (CARES) Act (Pub. L.

116–136) included a temporary moratorium on sequestration for all Medicare programs beginning on May 1, 2020 and ending on December 31, 2020, while section 102(a) of division N of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), extended the suspension period to March 31, 2021. An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes (Pub. L. 117–7), signed into law on April 14, 2021, extends the suspension period to December 31, 2021. Thus, we are proposing to amend § 512.255(c)(13) by removing the percentage amount and indicating that sequestration will be applied in accordance with applicable law.

We invite public comments on the application of sequestration.

c. Proposed National Base Rates

We codified at § 512.250(b) the criteria for excluding episodes, as more fully described in 85 FR 61183 through 61184. We finalized that we would exclude episodes in the baseline (currently proposed to be formally defined as ''baseline period'') that are not attributed to an RT provider or RT supplier. These episodes are exceedingly rare. There were fewer than 15 episodes out of more than 518,000 episodes in the 2016 to 2018 baseline period where the only RT delivery services in the episode were classified as professional services. There are a few brachytherapy surgery services that are categorized as professional services. We also finalized that episodes would be excluded if either the PC or TC is attributed to an RT provider or RT supplier with a U.S. Territory service location or to a PPS-exempt entity, but that services within an episode provided in a U.S. Territory or provided by a PPS-exempt entity would be included in the episode pricing. We finalized that episodes would be excluded if they include any RT service furnished by a CAH. Finally, we finalized that we would exclude all Maryland and Vermont claims before episodes are constructed and attributed to an RT provider or RT supplier, and we would similarly exclude inpatient and ASC claims from episode construction and attribution.

We finalized a policy that excluded claims before episodes were constructed in certain cases, while in other cases, we excluded entire episodes after construction if they included claims that were to be excluded. To simplify episode construction, attribution, and pricing, we propose to exclude all Maryland, Vermont, and U.S. Territory claims and all CAH, inpatient, ASC, and PPS-exempt claims in the same manner: Before episodes are constructed and attributed to an RT provider or RT supplier. Furthermore, to mirror the participant exclusion policy proposed in section XVIII.C.3 of this proposed rule, we are proposing to exclude all claims of an HOPD participating in PARHM (during the time period of their participation in PARHM) before episodes are constructed and attributed to an RT provider or RT supplier. We are also clarifying that we will exclude episodes from the RO Model's pricing methodology that are attributed to an RT provider or RT supplier that is located in a ZIP Code not assigned to a CBSA, not assigned an included cancer type, or that do not have more than $0 in total allowed amount for professional or technical services from Model pricing. We propose to amend § 512.250(b) accordingly.

We invite public comments on the proposal to exclude all Maryland, Vermont, and U.S. Territory claims and all CAH, inpatient, ASC, and PPS-exempt claims before episodes are constructed and attributed to an RT provider or RT supplier. We also invite public comments on the proposal to exclude all claims of an HOPD participating in PARHM (during the time period of their participation in PARHM) before episodes are constructed and attributed to an RT provider or RT supplier.

We finalized our policy in the Specialty Care Models Rule at 85 FR 61185 to change the baseline from 2015 to 2017 to 2016 to 2018 and finalized our national base rates for the model performance period based on the criteria set forth for cancer type inclusion are summarized in Table 3 of that final rule. As proposed in section XVIII.C.2. of this proposed rule, the baseline period would be updated to be the 3-year period within which episodes must initiate in order to be used in the calculation of the national base rates, participant-specific professional and technical historical experience adjustments, and participant-specific professional and technical case mix adjustments for PY1. The baseline period is January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in CY 2022, in which case the baseline period will be adjusted according to the new model performance period (that is, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

In conjunction with the publication of this proposed rule, we will provide a summary level, de-identified file titled the ''RO Episode File (2017 to 2019),'' on the RO Model website at *https://innovation.cms.gov/innovation-models/radiation-oncology-model* to further facilitate understanding of the RO Model's pricing methodology. We would like to clarify that the number of national base rates will vary based on how many cancer types are included in the RO Model.

Further, we are clarifying that Part B expenditures during the baseline period would be used to establish separate PC and TC national base rates for each of the included cancer types, the participant-specific historical experience adjustments for the model performance period, and the participant-specific case mix adjustments for PY1. The case mix adjustments for subsequent PYs (PY2 to PY5) would be calculated using the case mix model from the baseline period with the inputs coming from the beneficiary characteristics in episodes attributed to the participant in the most recent 3-year period that ends 3 years prior to the start of the CY to which the participant-specific case mix adjustment would apply. Our proposed national base rates for the model performance period are based on the criteria set forth for cancer type inclusion and are summarized in Table 58 of this proposed rule.

TABLE 58: National Base Rates

RO Model-Specific Codes	Professional or Technical	Included Cancer Type	National Base Rate
M1072	Professional	Anal Cancer	$3,104.11
M1073	Technical	Anal Cancer	$16,800.83
M1074	Professional	Bladder Cancer	$2,787.24
M1075	Technical	Bladder Cancer	$13,556.06
M1076	Professional	Bone Metastases	$1,446.41
M1077	Technical	Bone Metastases	$6,194.22
M1078	Professional	Brain Metastases	$1,651.56
M1079	Technical	Brain Metastases	$9,879.40
M1080	Professional	Breast Cancer	$2,059.59
M1081	Technical	Breast Cancer	$10,001.84
M1082	Professional	CNS Tumor	$2,558.46
M1083	Technical	CNS Tumor	$14,762.37
M1084	Professional	Cervical Cancer	$3,037.12
M1085	Technical	Cervical Cancer	$13,560.15
M1086	Professional	Colorectal Cancer	$2,508.30
M1087	Technical	Colorectal Cancer	$12,200.62
M1088	Professional	Head and Neck Cancer	$3,107.95
M1089	Technical	Head and Neck Cancer	$17,497.16
M1094	Professional	Lung Cancer	$2,231.40
M1095	Technical	Lung Cancer	$12,142.39
M1096	Professional	Lymphoma	$1,724.07
M1097	Technical	Lymphoma	$7,951.09
M1098	Professional	Pancreatic Cancer	$2,480.83
M1099	Technical	Pancreatic Cancer	$13,636.95
M1100	Professional	Prostate Cancer	$3,378.09
M1101	Technical	Prostate Cancer	$20,415.97
M1102	Professional	Upper GI Cancer	$2,666.79
M1103	Technical	Upper GI Cancer	$14,622.66
M1104	Professional	Uterine Cancer	$2,737.11
M1105	Technical	Uterine Cancer	$14,156.20

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d. Proposed Trend Factors

We codified our policy at § 512.255(c)(1) to apply a trend factor (an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for RT services) to each of the national base rates. For each PY, we will calculate separate trend factors for the PC and TC of each cancer type using data from HOPDs and freestanding radiation therapy centers not participating in the RO Model. Each of the separate trend factors will be updated and applied to the national base rates prior to the start of each PY (for which they would apply) so as to account for trends in payment rates and volume for RT services outside of the RO Model under OPPS and PFS. As finalized in the Specialty Care Models Rule, for the PC of each included cancer type and the TC of each included cancer type, we would calculate a trend factor as the ratio of: (a) Volume-weighted FFS payment rates for RT services included in that component for that cancer type in the upcoming PY (that is, the numerator) to (b) volume-weighted FFS payment rates for RT services included in that component for that cancer type in the most recent baseline year (that is, the denominator), which will be FFS rates from 2018. To calculate the

numerator, we finalized that we would multiply: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished for the most recent CY with complete data by (b) the corresponding FFS payment rate (as paid under OPPS or PFS) for the upcoming performance year.

To calculate the denominator, we finalized that we would multiply: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in 2018 (the most recent year used to calculate the national base rates) by (b) the corresponding FFS payment rate in 2018. The volume of HCPCS codes determining the numerator and denominator would be derived from non-participant episodes that would be otherwise eligible for Model pricing.

We would like to clarify that the number of separate trend factors will vary depending on the number of cancer types included in the RO Model. Further, given the delay in the model performance period and proposal to update the baseline period, we are proposing that the numerator of the trend factor be the product of (a) the component's FFS payment rate (as paid under OPPS or PFS) for the CY of the upcoming PY and (b) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished 3 years prior to the CY used to determine the FFS payment rates.

We are proposing the denominator of the trend factor be the product of (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in the most recent year of the baseline period and (b) the corresponding FFS payment rate for the most recent year of the baseline period. For example, for PY1, we would calculate the trend factor as: 2022 Trend factor = (2019 volume * 2022 corresponding FFS rates as paid under OPPS or PFS)/(2019 volume * 2019 corresponding FFS rates as paid under OPPS or PFS). As another example, for PY3, we would calculate the trend factor as: 2024 Trend factor = (2021 volume * 2024 corresponding FFS rates as paid under OPPS or PFS)/(2019 volume * 2019 corresponding FFS rates as paid under OPPS or PFS).

We would like to clarify that the trended national base rates will be made available on the RO Model website prior to the start of the applicable PY, after CMS issues the annual OPPS and PFS final rules that establish payment rates for the upcoming CY.

We finalized in the Specialty Care Models Rule at 85 FR 61188 the years used in the trend factor's numerator and denominator calculation. For example, the trend factor's numerator calculation for a model performance period that begins in 2021 is the most recent CY with complete data used to determine the average number of times each HCPCS code was furnished. The most recent CY with complete data in that case would have been 2018 for PY1, 2019 for PY2, and so forth. We noted that the corresponding FFS payment rate (as paid under the OPPS and PFS) included in the numerator calculation was still that of the upcoming PY (2021 payment rates for PY1, 2022 payment rates for PY2, and so forth). For a model performance period starting in 2021, the trend factor's denominator calculation would have used data from 2018 to determine: (a) The average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applying) was furnished; and (b) the corresponding FFS payment rate.

Given the delay in the model performance period and proposal to update the baseline period, we are proposing that the denominator of the trend factor be based on the third year of the proposed baseline period, and the numerator of the trend factor would be based on FFS payment rates for the same CY as the upcoming PY combined with utilization from the third year of the baseline period for PY1, the first CY after the baseline period for PY2, the second CY after the baseline period for PY3, and so on. For example, for a model performance period starting in 2022, the trend factor's denominator for PY1 would be based on 2019 FFS payment rates and 2019 utilization, while the numerator would be based on 2022 FFS payment rates and 2019 utilization. The trend factor's denominator would not change and remains based on 2019 FFS payment rates and 2019 utilization over the course of the model performance period. The numerator, however, would change, just as we described in the Specialty Care Models Rule (85 FR 61114). Its volume and utilization would be based on years that roll forward. For instance, for a model performance period starting in 2022, the numerator of the PY3 trend factor would be based on 2024 FFS payment rates and 2021 utilization.

We finalized at 85 FR 61187 through 61188 how RT services that are contractor-priced under Medicare PFS are incorporated into RO Model pricing. Due to the potential differences across jurisdictions, we would calculate the average paid amounts for each year in the baseline period for each of these RT services to determine their average paid amount that would be used in the calculation of the national base rates. We would use the most recent CY with claims data available to determine the average paid amounts for these contractor-priced RT services that would be used in the calculation of the trend factors for the PC and TC of each cancer type.

We would also like to clarify that we will use the allowed charges in the claims data to calculate these average paid amounts for contractor-priced RT services under Medicare PFS.

We invite public comments on the years used in the trend factor's numerator and denominator calculation.

e. Applying the Adjustments

We finalized our policy at 85 FR 61194 that the combined adjustment, that is the adjustment that results when the corresponding participant-specific historical experience and case mix adjustments, and blend are combined, be multiplied by the corresponding trended national base rate from Step 2 for each cancer type. We will repeat this calculation for the corresponding case mix adjustment, historical experience adjustment, and blend for the TC, yielding a total of 32 RO participant-specific episode payments for Dual participants and a total of 16 RO participant-specific episode payments for Professional participants and Technical participants. We are clarifying that the total number of RO participant-specific episode payments for Dual participants and the total number of RO participant-specific episode payments for Professional participants and Technical participants will vary depending on the number of included cancer types. For example, 15 included cancer types would yield a total of 30 RO participant-specific episode payment amounts for Dual participants and a total of 15 RO participant-specific episode payment amounts for Professional participants and Technical participants.

f. Proposal for HOPD or Freestanding Radiation Therapy Center With Fewer Than Sixty Episodes During the Baseline Period

We codified at § 512.255(c)(7)(iv) a stop-loss limit of 20 percent for the RO participants that have fewer than 60 episodes from 2016 through 2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of Specialty Care Models Rule (85 FR

61114). Under this stop-loss limit, CMS would use no-pay claims to determine what these RO participants would have been paid under FFS as compared to the payments they received under the RO Model and CMS would pay these RO participants retrospectively for losses in excess of 20 percent of what they would have been paid under FFS. Payments under the stop-loss policy would be determined at the time of reconciliation.

We propose to modify this stop-loss limit policy such that it applies to RO participants that have fewer than 60 episodes during the proposed baseline period and that were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation and amend § 512.255(c)(7)(iv) accordingly.

We invite public comments on this proposal that the stop-loss limit policy would apply to RO participants that have fewer than 60 episodes during the proposed baseline period and that were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

g. Proposal To Apply Adjustments for HOPD or Freestanding Radiation Therapy Center With a Merger, Acquisition, or Other New Business Relationship, With a CCN or TIN Change

We codified at § 512.210(a) those entities that must participate in the RO Model, and as more fully described at 85 FR 61195, an entity must participate in the RO Model if it has a new TIN or CCN that results from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2025, begins to furnish RT services within a CBSA selected for participation, and meets the RO Model's eligibility requirements. We finalized a requirement for advance notification regarding a new merger, acquisition, or other new clinical or business relationships so that the appropriate adjustments would be made to the new or existing RO participant's participant-specific professional episode payment and participant-specific technical episode payment amounts. We finalized that RO participants must also provide a notification regarding a new clinical relationship that may or may not constitute a change in control, and if there were sufficient historical data from the entities merged, absorbed, or otherwise changed as a result of this new clinical or business relationship, then this data would be used to determine adjustments for the new or existing TIN or CCN. We also note that RO participants are required to report a change in control under § 512.180(c).

We propose to add § 512.255(c)(14) that we would calculate in accordance with § 512.255(c)(3) the RO participant's case mix adjustments based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy TIN(s) or legacy CCN(s) during the 3-year period that determines the case mix adjustment for each PY and all episodes and RO episodes, as applicable, attributed to the RO participant's current TIN or CCN during the 3-year period that determines the case mix adjustment for each PY. We also propose to calculate the RO participant's historical experience adjustments in accordance with § 512.255(c)(4) based on all episodes attributed to the RO participant's legacy TIN(s) or legacy CCN(s) during the baseline period and all episodes attributed to the RO participant's current TIN or CCN during the baseline period. We propose to eliminate the requirement that RO participants provide a notification regarding all new clinical or business relationship that may or may not constitute a change in control. We continue to believe that some new or altered clinical or business relationships may still pose risks of gaming in the RO Model, regardless of whether a change in control results. However, we believe that requiring RO participants to report changes to TINs or CCNs will capture the types of changes that pose these risks. This would also avoid any ambiguity as to what types of changes RO participants would need to report. We are proposing to add § 512.210(e) requiring an RO participant to furnish to CMS written notice of a change in TIN or CCN in a form and manner specified by CMS at least 90 days before the effective date of any change in TIN or CCN that is used to bill Medicare.

We invite public comments on the proposal of how the case mix adjustments and historical experience adjustments are calculated for an entity that has a change in TIN or CCN. We also invite public comment on the proposal requiring an RO participant to furnish CMS written notice of a change in TIN or CCN.

h. Proposed Discount Factor

We codified at both §§ 512.205 and 512.255(c)(8) that the discount factor for the PC would be 3.75 percent and the discount factor for the TC would be 4.75 percent. We propose to lower the discount factor for the PC to 3.5 percent and the discount factor for the TC to 4.5 percent.

We believe that our proposals to remove brachytherapy from the list of included modalities and liver cancer from the included cancer types, if finalized, will enable us to lower these discounts without increasing the size of the RO Model due to a reduction in pricing variability. Given these proposed modifications to the RO Model, the proposed baseline period, and the current size of the RO Model (approximately 30 percent of eligible episodes), we now expect to be able to detect a savings of 3.2 percent or greater at a significance level of 0.05 and with a power of 0.8. If the proposals to remove brachytherapy and liver cancer are not both finalized, we would not finalize the lowered discounts as proposed.

The definition of discount factor codified at § 512.205 also included the finalized percentages. To simplify the regulation text, we propose to include the discount percentages at § 512.205 and remove the percentages from § 512.255(c)(8).

We invite public comments on these proposals related to the discount factor.

i. Proposed Withholds

We codified at § 512.255(c)(10) that we would apply a 2 percent quality withhold from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. In the CY 2021 OPPS/ASC final rule (85 FR 85866), we delayed RO Model quality measures requirements to what would have been PY2 (January 1, 2022 through December 31, 2022) under the model performance period described in that final rule with comment and thus delayed the application of the quality withhold to that PY2. In this proposed rule, we are proposing that RO participants submit quality measure data starting in PY1 (when the model performance period begins) as described in section XVIII.C.6 of this proposed rule, and that beginning in PY1, a 2 percent quality withhold for the PC would be applied to the applicable trended national base rates after the case mix and historical experience adjustments.

We invite public comment on the proposed timing of applying the quality withhold.

j. Proposed Adjustment for Geography

We described in the Specialty Care Models Rule (85 FR 61198) that the geographic adjustment whereby the RO Model-specific relative value unit (RVU) values would be derived from the national base rates which are based on

2016 to 2018 episodes that had the majority of radiation treatment services furnished at an HOPD and that were attributed to an HOPD. We finalized that we would use only 2018 episodes to calculate the implied RVU shares. (See RVUs shares in Table 59).

We propose to modify this provision to align with the proposed model performance period so that the final year of the baseline period would be used to calculate the implied RVU shares. For example, for a baseline period of 2017–2019, 2019 would be used to calculate the implied RVU shares.

We invite public comments on the proposal concerning the calculation of the RVU shares.

TABLE 59: RVU Shares:

RVU Shares					
Professional Component			Technical Component		
WORK	PE	MP	WORK	PE	MP
0.65	0.31	0.04	0	0.99	0.01

k. Example of Participant-Specific Professional Episode Payment and Participant-Specific Technical Episode Payment for an Episode Involving Lung Cancer in PY1

Table 60 and Table 61 are updated versions of Table 8 and Table 9 included in the Specialty Care Model Rule (85 FR 61201 and 85 FR 61202, respectively), that reflect the proposed updated national base rate for lung cancer and proposed discount rate for the respective component represented in each table.

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TABLE 60: Example: Participant-Specific Professional Episode Payment for Lung Cancer in PY1 (All numbers are illustrative only.)

	Professional Component	
	Amount	**Formula**
National Base Rate (a)	$2,231.40	
Trend Factor (b)	1.04	
Subtotal (c)	$2,320.66	c = a * b
SPLIT for SOE/EOE payments (d)	$1,160.33	d =c/2
Geographic Adjustment (e)	1.02	
Subtotal1 (f)	$1,183.53	f = d * e
Case Mix Adjustment (g)	0.02	e.g. (102-100) / 100
Historical Experience Adjuster (h)	0.14	e.g. (116-102) / 100
PY1 Blend (i)	0.90	
Adjustments combined (j)	1.15	j = g + (h * i) + 1
Subtotal (k)	$1,356.33	k = j * f
Discount Factor (l)	0.9650	
Subtotal (m)	$1,308.86	m = l * k
Withhold #1 (Incorrect Payment) (n)	0.99	
Withhold #2 (Quality Performance) (o)	0.98	
Total Withhold (p)	0.97	p = 1-((1-n)+(1-o))
Half of Total Episode Payment to RO Participant without sequestration (q)	$1,269.59	q = p * m
Beneficiary Coinsurance for SOE payment Determined (r)	$253.92	r = q * 0.20
SOE Participant Payment	$1,015.67	s = q * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment]	$995.36	t = s * 0.98
Episode Payment 1: SOE (u)*	**$995.36**	**u = t**
Episode Payment 2: EOE (v)*	**$995.36**	**v = t**
Total Episode Payment to RO Participant (w)	**$2,498.56**	**w = u+v+2r**

Please note that Table 60, which displays the participant-specific professional episode payment example, does not include any withhold amount that the RO participant would be eligible to receive back or repayment if more money was needed beyond the withhold amount from the RO participant. It also does not include any MIPS adjustment that applies to the RO participant.

TABLE 61: Example: Participant-Specific Technical Episode Payment for Lung Cancer in PY1 (All numbers are illustrative only.)

	Technical Component	
	Amount	**Formula**
National Base Rate (a)	$12,142.39	
Trend Factor (b)	1.04	
Subtotal (c)	$12,628.09	c = a * b
SPLIT for SOE/EOE payments (d)	$6,314.04	d =c/2
Geographic Adjustment (e)	1.02	
Subtotal1 (f)	$6,440.32	f = d * e
Case Mix Adjustment (g)	0.02	e.g. (102-100) / 100
Historical Experience Adjuster (h)	0.11	e.g. (113-102) / 100
PY1 Blend (i)	0.90	
Adjustments combined (j)	1.12	j = g + (h * i) + 1
Subtotal (k)	$7,206.72	k = j * f
Discount Factor (l)	0.9550	
Subtotal (m)	$6,882.42	m = l * k
Withhold #1 (Incorrect Payment) (n)	0.99	
Withhold #2 (Patient Experience) - not applied until PY3 (o)		
Total Withhold (p)	0.99	p = 1-((1-n)+(1-o))
Half of Total Episode Payment to RO Participant without sequestration (q)	$6,813.60	q = p * m
Beneficiary Coinsurance for SOE payment Determined (r)	$1,362.72	r = q * 0.20
SOE Participant Payment	$5,450.88	s = q * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment]	$5,341.86	t = s * 0.98
Episode Payment 1: SOE (u)*	**$5,341.86**	**u = t**
Episode Payment 2: EOE (v)*	**$5,341.86**	**v = t**
Total Episode Payment to RO Participant (w)	**$13,409.16**	**w = u+v+2r**

Table 61 details the participant-specific technical episode payment paid by CMS to a single TIN or single CCN for the furnishing of RT technical services to an RO beneficiary for an RO episode of lung cancer. The participant-specific technical episode payment in this example does not include any rural sole community hospital adjustment that the RO participant would be eligible to receive. Also, please note that for the participant-specific technical payment amount, the beneficiary coinsurance cannot exceed the inpatient deductible limit under OPPS.

We are currently analyzing whether the COVID–19 pandemic resulted in a decrease in Medicare FFS claims submissions for RT services during 2020 relative to historical levels. For this reason, under the extreme and uncontrollable policy proposed in section XVIII.C.10 of this proposed rule, pending 12-months of claims run-out for RT services furnished in 2020, we will consider the removal of 2020 data from the calculation of any applicable baseline period or trend factor. We are not considering the exclusion of 2020 from the case mix adjustment at this time, because the case mix episodes are weighted equally (unlike the baseline period, where more recent episodes are given more weight than earlier episodes), and the case mix adjustment does not rely on the volume of RT services furnished.

We solicit comments on this approach to addressing utilization during the 2020 EUC.

We are also providing Table 62, which is an example that summarizes the data sources and time periods used to determine the values of key pricing components for a baseline period of 2017 through 2019 as a result of the proposed modifications to the pricing methodology.

TABLE 62: Data Sources and Time Periods Used to Determine Values of the RO Model's Key Pricing Components for a Baseline Period of 2017 through 2019

Key Components	Data Source	PY 1 (2022)	PY 2 (2023)	PY 3 (2024)	PY 4 (2025)	PY 5 (2026)
National Base Rates	HOPD episodes	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
Trend factor	Non-participant episodes	(2019 volume * 2022 rates) / (2019 volume * 2019 rates)	(2020 volume * 2023 rates) / (2019 volume * 2019 rates)	(2021 volume * 2024 rates) / (2019 volume * 2019 rates)	(2022 volume * 2025 rates) / (2019 volume * 2019 rates)	(2023 volume * 2026 rates) / (2019 volume * 2019 rates)
Winsorization thresholds	HOPD episodes	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
Case mix coefficients	HOPD episodes	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
Case mix values [and whether eligible (>60 episodes) to receive case mix adjustment]	Participant-specific	2017-2019	2018-2020	2019-2021	2020-2022	2021-2023
Historical Experience adjustment [and whether eligible (>60 episodes) to receive historical experience adjustment]	Participant-specific	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019

Key Components	Data Source	PY 1 (2022)	PY 2 (2023)	PY 3 (2024)	PY 4 (2025)	PY 5 (2026)
Blend for RO participant with historical experience adjustment greater than 0.0	N/A	0.90	0.85	0.80	0.75	0.70
Blend for RO participant with historical experience adjustment equal to or less than 0.0	N/A	0.90	0.90	0.90	0.90	0.90
RVU shares used in the PFS geographic adjustment	HOPD episodes	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2019	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2019	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2019	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2019	WORK/PE/MP shares PC (66/30/4) TC (0/99/1) 2019
Low Volume Opt-Out Eligibility (<20 episodes)	Participant-specific	2020	2021	2022	2023	2024

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6. Quality—Proposed Form, Manner, and Timing for Quality Reporting

We finalized that the RO Model quality measure reporting to be based on a CY of data (85 FR 61220 through 61223). In the CY 2021 OPPS/ASC final rule, we delayed RO Model quality measures requirements to PY2 (January 1, 2022 through December 31, 2022). In this proposed rule, we are proposing that Professional participants and Dual participants submit quality measure data starting in PY1 during the proposed model performance period. Under this proposal, if the proposed model performance period starts mid-year, the CY collection period would remain. For example, if the model performance period starts in July, RO participants would collect quality measure data for that CY starting in January. This would allow RO participants to use their MIPS data submission to meet the RO Model requirements. We are proposing this policy because we believe that any segmentation to reflect data from only the portion of the CY in PY1 would be inconsistent with the measure, and add

substantial reporting burden to RO participants.

For PY1, Professional participants and Dual participants would be required to submit data for three pay-for-performance measures: (1) Plan of Care for Pain; (2) Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan. Professional participants and Dual participants would be required to submit data on a fourth measure, Treatment Summary Communication—Radiation Oncology, as a pay-for-reporting measure. All quality measure data is reported using the RO Model secure data portal in the manner consistent with that submission portal and the measure specification.

Data submitted by Professional participants and Dual participants for the Treatment Summary Communication—Radiation Oncology measure will be used to propose a benchmark to re-specify it as a pay-for-performance measure, for PY3.

We are proposing that we may update the specifications for the Treatment Summary Communication—Radiation Oncology measure, should new specifications from the measure's steward meet the RO Model's needs. Any non-substantive updates to the specifications for this measure would be communicated in a form and manner specified by CMS. Any substantive changes to measure specifications would be addressed through notice and comment rulemaking.

We also finalized that we would have a CMS-approved contractor administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Survey for Radiation Therapy, beginning in April 2021 (85 FR 61220). In the CY 2021 OPPS/ASC final rule, we revised this policy so that a CMS-approved contractor would administer the CAHPS® Cancer Care Survey for Radiation Therapy beginning in October 2021. Given the change in model performance period due to the delay under section 133 of the CAA 2021, we are proposing that we amend existing policy such that the CMS-approved contractor will begin administering the CAHPS® Cancer Care Survey for Radiation Therapy on behalf of the RO participants and CMS as soon as there are completed RO episodes, no earlier than the fourth month of the model performance period.

We finalized under the RO Model's clinical data collection policy that Professional participants and Dual participants must collect certain clinical information not available in claims or quality measures, with data collecting starting in PY1 (85 FR 61223 through 61226). In the CY 2021 OPPS/ASC final rule, we revised this policy so that the collection period for clinical data elements (CDEs) would begin on January 1, 2022. In this proposed rule, we are proposing that Professional participants and Dual participants submit CDEs starting in PY1.

We invite public comments on these proposals, including whether there are associated changes to the burden or costs with submitting CDEs.

7. The RO Model as an Advanced Alternative Payment Model (Advanced APM) and a Merit-Based Incentive Payment System APM (MIPS APM)

We finalized in the Specialty Care Models Rule at 85 FR 61238 that we expected the RO Model to meet the criteria to be an Advanced APM and a MIPS APM under the Quality Payment Program beginning in PY1 of the RO Model, on January 1, 2021. In CY 2021 OPPS/ASC final rule (85 FR 86262), we amended this policy to reflect that we anticipated that the RO Model will meet the criteria to be both an Advanced APM and a MIPS APM under the Quality Payment Program starting in PY2 which would begin on January 1, 2022. Despite the delay required by section 133 of the CAA 2021, we expect the RO Model to meet the criteria to be an Advanced APM and a MIPS APM beginning in PY1, beginning January 1, 2022. Final CMS determinations of Advanced APMs and MIPS APMs for the 2022 performance period will be announced via the Quality Payment Program website at *https://qpp.cms.gov/*. We anticipate that the RO Model will meet the Advanced APM criteria, reflected in our regulation at § 414.1415 in PY1 and all subsequent PYs.

The first criterion to be an Advanced APM is set forth at § 414.1415(a), CEHRT use. For the RO Model, this criterion is satisfied by the requirements of § 512.220(b), that participants must use CEHRT; that the RO participant must annually certify its use of CEHRT during the model performance period; and that the RO participant will be required to certify its use of CEHRT within 30 days of the start of each PY.

The second criterion to be an Advanced APM is at § 414.1415(b), Payment based on quality measures. This criterion is satisfied because payment under the RO Model is based on MIPS-comparable quality measures, as specified in regulation at § 414.1415(b). Specifically, the RO participant will have their payment amount adjusted by the 2 percent quality withhold with the chance of earning back some or all of that amount based on their AQS, as codified at § 512.255(c)(10). For further discussion of these requirements, please see 85 FR 61211 through 61231.

The third criterion to be an Advanced APM is set forth at § 414.1415(c), Financial Risk. This criterion is satisfied by the application of the discount factor to RO Model payments, codified at § 512.255(c)(8); the application of the quality withhold to the RO Model payments, codified at § 512.255(c)(10); and the fact that RO participants are responsible for 100 percent of all expenditures in excess of the expected amount of expenditures beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment as codified at § 512.265, with the exception of those RO participants that qualify for the stop-loss policy as codified at § 512.285(f). The proposed changes to the stop-loss policy described in section XVIII.C.5.f and the discount amounts described in section XVIII.C.5.h of this proposed rule do not affect the satisfaction of the Financial Risk criterion.

As finalized in the CY 2021 OPPS/ASC final rule at 85 FR 61237, for the subset of RO participants that are limited to the total amount of losses they may incur because they are eligible for the stop-loss policy, that limit is set to 20 percent of expected expenditures for which the RO participants are responsible for under the RO Model. Therefore, even when the RO Model stop-loss policy is applicable, the RO Model still meets the Financial Risk criterion to be an Advanced APM, which is 3 percent of the expected expenditures for which an APM Entity is responsible under the APM, at § 414.1415(c)(3)(i)(B).

The RO Model would also meet the criteria to be a MIPS APM under the definition at § 414.1305 starting January 1, 2022. Any MIPS eligible clinician who is included on the individual practitioner list as described at § 512.217 may report and be scored for MIPS as part of an APM Entity, and through the APM Performance Pathway described at § 414.1367.

The MIPS APM criteria at § 414.1367(b) specify that APM entities in a MIPS APM must participate in the APM under an agreement with CMS or through a law or regulation, and the APM must base payment on quality measures and cost/utilization. Professional participants and Dual participants are required to report quality measures, as codified at § 512.275(c), and the RO Model meets the quality measure and cost/utilization requirement through the application of the quality withhold, codified at § 512.255(c)(10), and the use of the

Aggregate Quality Score (AQS) and its application to the quality withhold, as finalized at 85 FR 61226 through 61231. Pursuant to §§ 414.1317 and 414.1367, MIPS eligible clinicians who are identified on a participation list of an APM Entity participating in a MIPS APM during the performance period have unique reporting options under MIPS.

We are clarifying that Professional participants and Dual participants who meet the RO Model requirements codified at § 512.220, including use of CEHRT, and who are eligible clinicians on a Participation List as those terms are defined at § 414.1305, will fall into a category called ''Track One'' of the RO Model. We propose to define ''Track One'' to mean an Advanced APM and MIPS APM track for Dual participants and Professional participants that use CEHRT. RO Model participants in Track One will be considered to be participating in the Advanced APM track of the RO Model, and we will make Qualifying APM Participant (QP) determinations for the eligible clinicians on the RO Model Participation List for Track One as provided in § 414.1425. If eligible clinicians who are Track One RO Participants do not meet the thresholds to become QPs, they will be considered to be participating in a MIPS APM and can report to MIPS using reporting options applicable to MIPS APM participants as specified at § 414.1367. At the start of a PY, if Professional participants or Dual participants fail to meet any of the RO Model requirements codified at § 512.220, which includes use of CEHRT, they will be moved into a separate category called ''Track Two'' of the RO Model for that PY. We propose to define ''Track Two'' to mean an APM for Dual participants and Professional participants who do not meet the RO Model requirements set forth at § 512.220; and for all Technical participants. RO participants that fall into Track Two will not be participating in an Advanced APM or MIPS APM for the RO Model. As such, we will not make QP determinations for the eligible clinicians on the RO Model Participation List for Track Two. We are proposing to codify definitions for ''Track One'' and ''Track Two'' at § 512.205. If an RO participant meets the CEHRT use requirements pursuant to § 414.1415(a)(1)(i) by the last QP determination snapshot date specified at § 414.1325, they will be moved to Track One of the RO Model and considered at that point to be participating in an Advanced APM, provided the RO participant meets all other RO Model requirements set forth at § 512.220.

We recognize that any failure, however minor, to comply with the RO Model requirements set forth at § 512.220(a)(2) will have an impact on whether an RO Model participant is in Track One versus Track Two. Section 512.220(a)(2) contains a number of requirements, including requirements to discuss goals of care and RO Model cost-sharing responsibilities with each RO beneficiary; adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate; assess each RO beneficiary's tumor, note, and metastasis cancer stage; and send a treatment summary to each RO beneficiary's referring physician within 3 months of the end of the treatment. Under our proposal, any failure to comply with the requirements of § 512.220(a)(2) will result in Track Two status for the RO participant and would be subject to remedial action under § 512.160. However, we recognize that an RO participant's noncompliance with the terms of § 512.220(a)(2) might not be discovered until after CMS has treated the RO participant as if they were in Track One, including potentially making QP determinations for an RO participant's eligible clinicians and making APM Incentive Payments (or, in years beginning with CY 2026, applying a differentially higher update under the physician fee schedule). In that event, the payments we would make based on the QP status of the RO participant's eligible clinicians pursuant to its Track One status would constitute overpayments. We are concerned that, in the case of minor noncompliance with the requirements of § 512.220(a)(2), such overpayment liability may be too harsh. We considered removing the requirement that RO Model participants must meet all of the requirements codified in § 512.220(a)(2) to remain in Track One, but feel that these requirements are important to quality improvement in radiation oncology. Nevertheless, we are considering whether the final rule should modify some of the requirements in § 512.220(a)(2). For example, instead of requiring certain actions for ''each RO beneficiary,'' we are considering whether to require those actions for a majority of RO beneficiaries or substantially all RO beneficiaries. In addition, we are considering whether the final rule should modify certain requirements to permit payment of some or all of the payments made based on the QP status of the RO participant's eligible clinicians pursuant to its Track One participation, depending on the severity of noncompliance and other factors.

We welcome comments on these considerations, including whether the RO Model can meaningfully improve the quality of care if any of the requirements specified in § 512.220(a)(2) are modified, which requirements would be appropriate for modification, the impact of recoupment, and if there are more effective ways to encourage quality improvement and Track One participation.

a. Technical Participants and the Quality Payment Program

Technical participants that are freestanding radiation therapy centers (as identified by a TIN) that only provide the technical component (TC) are not required to report quality measures under the RO Model and fall into Track Two of the RO Model. Technical participants will not be considered to be participating in Advanced APMs or MIPS APMs under the RO Model. However, Technical participants can attest to their participation in an APM for purposes of MIPS, and may be eligible to receive Improvement Activity credit as specified at § 414.1317(b)(3).

We are also proposing that if the Technical participants that are freestanding radiation therapy centers (as identified by a TIN) begin providing the PC at any point during the model performance period, then they must notify CMS within 30 days, in a form and manner specified by CMS. We propose that they would also be required under the RO Model to report quality measures by the next reporting period, which would be March of a PY for Quality Measures and January and July of a PY for the clinical data elements, as finalized at 85 FR 61211 through 61231. If they meet the requirements to be a Track One RO Model participant at one of the QP determination dates specified in § 414.1425(b), they would be considered to be participating in an Advanced APM and a MIPS APM. Once a Technical participant that is a freestanding radiation therapy center begins providing the professional component, the freestanding radiation therapy center becomes a Dual participant as defined in § 512.205. We will monitor these RO participants for compliance with the requirement to report quality measures if they begin providing the professional component. We are proposing to codify this policy at § 512.275(d).

We invite public comments on these proposals related to Technical

participants that are freestanding radiation therapy centers.

b. Individual Practitioner List

We codified the requirements concerning the review and certification of the individual practitioner list at § 512.217. In CY 2021 OPPS/ASC final rule (85 FR 86262), we amended this regulation so that the individual practitioner list was not to be used for QP determinations or for determining participants in a MIPS APM for purposes of MIPS reporting and scoring rules in PY1, and the individual practitioner list was to only be used for the Quality Payment Program in PY1 to assign an automatic 50 percent score for the Improvement Activity performance category in MIPS for RO participants. This amendment stated that starting in PY2 (January 1, 2022), the individual practitioner list was to be used to identify the relevant eligible clinicians for purposes of making QP determinations and for certain aspects of MIPS under the Quality Payment Program. Section 133 of the CAA 2021 prohibits implementation of the RO Model prior to January 1, 2022. In this proposed rule, we are clarifying that all requirements concerning the review and certification of the individual practitioner list finalized and codified at § 512.217 will remain in effect starting on the first day of the model performance period.

We codified at § 512.217(a) that upon the start of each PY, CMS creates and provides to each Dual participant and Professional participant an individual practitioner list which identifies by NPI each individual practitioner associated with the RO participant.

We are proposing to modify this policy to include that Technical participants that are freestanding radiation therapy centers will also be provided an individual practitioner list. We are also proposing to add to the regulation at § 512.217(b) that in the case of a Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center, which begins participation in the RO Model after the start of a given PY, but at least 30 days prior to the last QP determination snapshot date specified at § 414.1325, of that PY, CMS would create and provide the new Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center with an individual practitioner list. Any new Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center that begins participation in the RO Model after the start of the PY must review and certify their individual practitioner list by the last QP determination snapshot date specified at § 414.1325.

We are proposing to change this policy to be inclusive of new RT providers and RT suppliers that would be required to participate in the RO Model after the start of a PY; we believe this proposal will give all RO participants, including those that begin participation in the RO Model after the start of a PY, more time to review and certify their individual practitioner lists.

We invite public comments on reviewing and certifying individual practitioner lists.

We codified at § 512.217(b) and (c)(1) that the RO participant must review and certify the individual practitioner list within 30 days of receipt of the individual practitioner list. We also codified at § 512.217(d)(1)(i) and (d)(2)(i) that the RO participant must notify CMS within 30 days when there are any additions or removals of eligible clinicians to the individual practitioner list. We are proposing to modify these policies so that RO participants will have the ability to review their individual practitioner list and add or drop the necessary NPIs from the list up until the last QP determination snapshot date specified at § 414.1325. We are proposing to change this policy to give RO participants more time to review and certify their individual practitioner lists by requiring this by the last QP determination snapshot date specified at § 414.1325, instead of within 30 days of receipt of the individual practitioner list.

We invite public comments on this proposal to modify the timeframe for which individual practitioner lists shall be certified.

We codified at § 512.217(c)(3) that if the Dual participant or Professional participant does not verify and certify the individual practitioner list by the deadline specified by CMS, RO participants on the unverified list are not recognized as participants on a participation list of either a MIPS APM or Advanced APM. We are proposing to add § 512.217(c)(3)(iii) that if individual practitioners who participate in the RO Model with Technical participants that are freestanding radiation therapy centers are not included on a verified list they will not be eligible to receive Improvement Activity credit under MIPS.

We invite public comments on this proposal to add § 512.217(c)(3)(iii).

c. RO Model Requirements

We codified at § 512.220(b) that RO participants must use CEHRT, that the RO participant must annually certify its use of CEHRT during the model performance period, and that the RO participant will be required to certify its use of CEHRT within 30 days of the start of each PY. In CY 2021 OPPS/ASC final rule (85 FR 86262), we amended the CEHRT requirement beginning in PY2, on January 1, 2022, and to be required for PY2 through PY5. However, section 133 of the CAA 2021 prohibits implementation of the RO Model prior to January 1, 2022.

Accordingly, we are proposing that the CEHRT requirement would begin in PY1 of the proposed model performance period and that RO participants must certify their use of CEHRT at the start of PY1 and each subsequent PY, as codified at § 512.220(b)(1) and (2). We are proposing to codify at § 512.220(b)(3) that if an RO participant begins participation in the RO Model at any time during an ongoing PY, they must certify their use of CEHRT by the last QP determination snapshot date specified at § 414.1325.

We codified at § 512.220(a)(1) that RO participants must satisfy the requirements set forth at § 512.220 to qualify for the APM Incentive Payment. We propose to amend § 512.220(a)(1) to state that RO participants must satisfy the requirements set forth at § 512.220 to be included in Track One of the RO Model. If RO participants do not meet those requirements in a PY, the participant will be in Track Two for the applicable PY. This proposed change is necessary to align with the Quality Payment Program.

We invite public comments on these proposals related to compliance with the CEHRT requirements and the other requirements as conditions to be included in Track One of the RO Model.

8. Proposed Reconciliation Process

a. Initial Reconciliation

Reconciliation is the process to calculate reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services. We stated in the Specialty Care Models Rule at 85 FR 61243 that we would conduct the initial reconciliation for PY1 as early as August 2022, and the PY2 initial reconciliation as early as August 2023, and so forth. Given the proposed change in model performance period due to the delay under section 133 of the CAA 2021, we expect to conduct the initial reconciliation each August for the preceding PY. For example, for PY1, we would conduct the initial reconciliation as early as August of PY2.

In the CY 2021 OPPS/ASC final rule we amended § 512.285(d) such that the

quality reconciliation payment amount would not be applicable for PY1, because there would not be a quality withhold in PY1. Given the proposed change in model performance period due to the delay under section 133 of the CAA 2021, and our proposal that the application of a quality withhold would begin in PY1 as described in section XVIII.C.5 of this proposed rule, we propose to amend § 512.285(d) such that the quality reconciliation payment amount will apply to all PYs. We invite public comments on our proposal.

b. True-Up Reconciliation

The true-up reconciliation is the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run-out for all RO episodes initiated in the applicable PY. We stated in the Specialty Care Models Rule at 85 FR 61244 that we would conduct the PY1 true-up reconciliation as early as August 2023, and the PY2 true-up reconciliation as early as August 2024, and so forth. Given the proposed change in model performance period due to the delay under section 133 of the CAA 2021, we expect to conduct the true-up reconciliation as early as August of the CY following an initial reconciliation for a PY. For example, for PY1, we would conduct the true-up reconciliation as early as August of PY3.

c. Proposed Reconciliation Amount Calculation

We codified at § 512.285(c)(3) that a subset of incomplete episodes in which (1) the TC is not initiated within 28 days following the PC; (2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which a TC is initiated, even if that date is within 28 days following the PC; or (3) the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished, the RO participant would be owed only what it would have received under FFS for the RT services furnished to that RO beneficiary. CMS would reconcile the episode payment for the PC and TC that was paid to the RO participant with what the FFS payments would have been for those RT services using no-pay claims. Furthermore, we finalized in the case that traditional Medicare ceases to be the primary payer for an RO beneficiary after the TC of the RO episode has been initiated but before all included RT services in the RO episode have been furnished, each RO participant would be paid only the first installment of the episode payment. The RO participant would not be paid the EOE PC or TC for these RO episodes.

We are proposing to modify this policy such that for all incomplete episodes as defined at § 512.205, including when the RO beneficiary ceases to have traditional FFS Medicare before all included RT services in the RO episode have been furnished, CMS would reconcile the episode payment for the PC and TC that was paid to the RO participant(s) with what the FFS payments would have been for those RT services using no-pay claims. After reviewing data for incomplete episodes, including incomplete episodes where an RO beneficiary ceases to have traditional FFS Medicare before the end of an episode, we determined that the data did not support paying RO participants only the first installment of an episode for this type of incomplete episode. Upon further review of this data and stakeholder comments on this policy we propose to amend § 512.285(c)(3) and (4) accordingly.

In light of the proposal to modify payment for incomplete episodes, we are proposing conforming changes to § 512.255(c)(12)(iv) regarding beneficiary coinsurance for incomplete episodes. Specifically, we propose to modify § 512.255(c)(12)(iv) to specify that the coinsurance for all incomplete episodes is 20 percent of the FFS amount applicable to the RT services that were furnished.

We codified at § 512.205 a definition for ''stop-loss reconciliation amount'' to mean the amount owed to RO participants that have fewer than 60 episodes during 2016 through 2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of the Specialty Care Models Rule for the loss incurred under the RO Model as described in § 512.285(f). We propose to modify the definition for ''stop-loss reconciliation amount'' to mean the amount owed to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation for the loss incurred under the RO Model as described in § 512.285(f), in order to make this definition consistent with the updated model performance period.

We invite public comments on these proposals related to the reconciliation amount calculation.

9. Potential Overlap With Other Models Tested Under Section 1115A Authority and CMS Programs

In the Specialty Care Models Rule (85 FR 61258), we stated that we did not envision that the prospective episode payments made under the RO Model would need to be adjusted to reflect payments made under any of the existing models being tested under section 1115A of the Act or the Medicare Shared Savings Program (Shared Savings Program) under section 1899 of the Act. We also stated that if, in the future, we determined that such adjustments are necessary, we would propose overlap policies for the RO Model through notice and comment rulemaking. However, we did not codify this policy in the regulations for the RO Model at that time. The RO Model is not a total cost of care model, and includes only RT services in the episode payment. The RO Model's payments are narrow in scope because they are limited to RT services furnished during a distinct period of time. Because the RO Model makes prospective payments for only RT services provided during an episode, a practice participating in the RO Model would receive the same prospective episode payment for RT services regardless of its participation in other CMS models or programs.

Thus, at this time, we continue to see no need to adjust the prospective episode payments made under the RO Model to reflect payments made under the Shared Savings Program or under any other models tested under section 1115A of the Act. We are proposing to codify this policy on overlaps at § 512.292. The financial methodology and accounting policies under the applicable model tested under section 1115A of the Act or the Shared Savings Program will continue to govern the way in which RO Model payments are factored into reconciliation calculations for that initiative. We believe that other initiatives that use a total cost of care approach could consider taking the necessary steps to update their financial methodologies to adjust for the RO Model payments, but we note that the RO Model payments may only be a small portion of the population's overall payments.

We invite public comments on this proposal to codify our overlap policy.

10. Proposed Extreme and Uncontrollable Circumstances Policy

The nation, its communities, and its health care providers, on certain occasions, are forced to confront extreme and uncontrollable circumstances outside of their control that impact their ability to operate in the ordinary course of business for short-term or sometimes even extended periods. The U.S. is currently responding to an outbreak of respiratory disease caused by a novel coronavirus,

referred to as ''COVID–19'', which has created serious public health threats that have greatly impacted the U.S. health care system, presenting significant challenges for stakeholders across the health care delivery system and supply chain. Other extraordinary events that have a disruptive impact may also occur in the future. These events may include other public health emergencies, large-scale natural disasters (such as, but not limited to, hurricanes, tornadoes, and wildfires), or other types of disasters. Such events may strain health care resources, and CMS understands that RT providers and RT suppliers may have limited capacity to continue normal operations and fulfill RO Model participation requirements under such circumstances.

Therefore, we propose to adopt an extreme and uncontrollable circumstance policy for the RO Model which would allow CMS to revise the model performance period; grant certain exceptions to RO Model requirements to ensure the delivery of safe and efficient health care; and revise the RO Model's payment methodology.

a. Extreme and Uncontrollable Circumstance Affects the Nation, Region, or a Locale

We propose to define an extreme and uncontrollable circumstance (EUC) as a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale. We propose that if CMS declares an EUC for a geographic region, CMS may: (1) Amend the model performance period; (2) eliminate or delay certain reporting requirements for RO participants; and (3) amend the RO Model's pricing methodology. Application of the modifications would be based on the severity and types challenges that the circumstance imposes on RO participants. In every circumstance, CMS would seek to minimize impact on the RO participants not affected by the EUC, while supporting those that are affected.

In a national, regional, or local event, we would apply the extreme and uncontrollable circumstance policy only if the magnitude of the event calls for the use of special authority to help providers respond to the emergency and continue providing care. We would not use a bright-line test to assess all types of public health emergencies, disasters, or other extraordinary circumstances; application of the policy would be tailored to the specific circumstance, and to the affected geographic areas. To help identify RO participants that are experiencing an extreme and uncontrollable circumstance, CMS would consider the following factors:

- Whether the RO participants are furnishing services within a geographic area considered to be within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Social Security Act.
- Whether the geographic area within a county, parish, U.S. territory, or tribal government designated under the Stafford Act served as a condition precedent for the Secretary's exercise of the 1135 waiver authority, or the National Emergencies Act.
- Whether a state of emergency has been declared in the relevant geographic area.

In the event that one or more of these conditions are present, CMS would announce that the extreme and uncontrollable circumstances policy applies to one or more RO participants within an affected geographic area. CMS would communicate this decision via the RO Model website and written correspondence to RO participants.

We invite public comment on the definition of EUC.

b. Model Performance Period

In instances where an EUC is nation-wide and impacts RO participants' ability to implement the requirements of the RO Model at the start of the model performance period, we propose that CMS may delay the start date of the model performance period by up to one CY. RO participants would be notified of any changes to the model performance period on the RO Model website no later than 30 days prior to the original start date. In the case where a delay to the RO Model performance period is required because of an EUC, various other aspects of the RO Model may be impacted, including its status as an Advanced APM and the years that would be included in the baseline period. The implications of a model performance period delay on other aspects of the RO Model would also be included in the RO Model website notification no later than 30 days prior to the original start date. In the case of a regional EUC, we propose to not change the model performance period, but instead only to delay or exempt requirements, as discussed in section XVIII.C.10.c for the RO participants in the impacted region.

We invite public comment on this proposal related to when we would amend the model performance period.

c. Reporting Requirements

Quality Measures and Clinical Data Elements: If an EUC impacts RO participants' ability to comply with the RO Model's quality measure or clinical data element reporting requirements, we propose that CMS may delay or exempt the affected RO participants from the reporting requirements, make the requirements optional, and/or extend the time for RO participants to report data to CMS, as applicable. CMS would modify or grant exceptions to the RO Model's reporting requirements if, for example, affected RO participants cannot submit their quality and clinical data reporting due to electricity or internet outages caused by an EUC.

Other Participation Requirements: Because RO participants must focus on direct care, we propose that CMS may waive compliance with or adjust the requirement that RO participants actively engage with an AHRQ-listed patient safety organization (PSO) and provide Peer Review (audit and feedback) on treatment plans.

We invite public comment on these proposals related to reporting requirements during an EUC.

d. Pricing Methodology

Adjusting the Quality Withhold: If CMS decides to remove (not merely extend) quality and clinical data submission requirements for affected RO participants due to a national, regional, or local event, we propose that CMS could choose to repay the quality withhold during the next reconciliation, and award all possible points in the subsequent AQS calculation for affected RO participants, which would potentially increase episode payments during this time.

Trend Factor Adjustments: In situations where RO participants nation-wide experience significant, aggregate-level disruptions to their service utilization, in that the trend factor (specific to a cancer type and component) for the upcoming PY has increased or decreased by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payment rates are held constant with the previous CY, we propose that CMS may modify the trend factor calculation for the PC and/or TC of an included cancer type.

For example, for PY2, a change in the trend factor calculation for the PC and/or TC of an included cancer type could be warranted if [(2020 volume * 2022 rates)/(2019 volume * 2019 rates)] is more than 10 percent change from [(2019 volume *2022 rates)/(2019 volume * 2019 rates)]. The 10 percent

change threshold aligns with the 10 percent criterion for removing an included cancer type, whereby if CMS discovers a ≥10 percent (≥10%) error in established national base rates, the cancer type will be removed from the RO Model. If CMS were to implement this modification, CMS would ensure that the trend factor calculation is most consistent with the average utilization from the previous CY. We propose to codify the extreme and uncontrollable circumstances policies at § 512.294.

We invite public comments on these proposals related to changes in the pricing methodology due to an EUC.

XIX. Proposed Updates to Requirements for Hospitals To Make Public a List of Their Standard Charges

A. Introduction and Overview

1. Statutory Basis and Background

Section 1001 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), amended Title XXVII of the Public Health Service Act (the PHS Act), in part, by adding a new section 2718(e). Section 2718 of the PHS Act, entitled ''Bringing Down the Cost of Health Care Coverage,'' requires each hospital operating within the United States (U.S.) for each year to establish (and update) and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act (the Act). Section 2718(b)(3) of the PHS Act requires the Secretary of the Department of Health and Human Services (Secretary) to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties.

As published in the **Federal Register**, the final rule entitled ''CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals to Make Standard Charges Public'' (84 FR 65524 (November 27, 2019), herein referred to as the CY 2020 Hospital Price Transparency final rule), we implemented these sections by adopting requirements for hospitals to make public their standard charges in two ways: (1) As a comprehensive machine-readable file; and (2) in a consumer-friendly format. We codified these requirements at new 45 CFR part 180.

In the CY 2020 Hospital Price Transparency final rule, we indicated that we believe our policies requiring public release of hospital standard charge information are a necessary and important first step in ensuring transparency in health care prices for consumers, although we also recognized that the release of hospital standard charge information would not be sufficient by itself to achieve the ultimate goals for price transparency. The final regulations were designed to begin to address some of the barriers that limit price transparency with a goal of increasing competition among healthcare providers to bring down costs. In particular, the regulations sought to address the barriers related to lack of hospital standard charge data by requiring some uniformity in the release of hospital standard charge information. We indicated our belief that more work would need to be done to ensure consumers have access to the information they need to make healthcare decisions. We therefore encouraged hospitals and other health care providers to go further in addressing barriers to price transparency.

2. Summary of Proposals

We are proposing to amend several hospital price transparency policies codified at 45 CFR part 180 in order to encourage compliance. For the reasons explained in this section of the preamble, we are proposing to: (1) Increase the amount of the penalties for noncompliance through the use of a proposed scaling factor based on hospital bed count; (2) deem state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180, and (3) prohibit certain conduct that we have concluded are barriers to accessing the standard charge information. We believe these proposed modifications are responsive to stakeholders and are necessary to ensure compliance with the hospital price transparency disclosure requirements. We are also clarifying the expected output of hospital online price estimator tools, an issue that occurs with respect to a hospital that chooses to use an online price estimator tool in lieu of posting its standard charges for the required shoppable services in a consumer-friendly format. Finally, we are seeking comment on a variety of issues that we may consider to improve standardization of the data disclosed by hospitals.

B. Proposal To Increase the Civil Monetary Penalty Amounts Using a Scaling Factor

Section 2718(b)(3) of the PHS Act requires the Secretary to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties. In the CY 2020 Hospital Price Transparency final rule (84 FR 65581 through 65590), we established monitoring and enforcement policies at new 45 CFR part 180, subpart C. Specifically, we finalized a process for monitoring hospital compliance with section 2718(e) of the PHS Act, by evaluating complaints made by individuals or entities to the Centers for Medicare & Medicaid Services' (CMS), reviewing individuals' or entities' analysis of noncompliance, and auditing hospitals' websites. Should CMS conclude a hospital is noncompliant with one or more of the requirements to make public standard charges, CMS may take any of the following actions, which generally, but not necessarily, will occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s).
- Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements.
- Impose a civil monetary penalty not in excess of $300 per day, on the hospital and publicize the penalty on a CMS website if the hospital fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan.

As described in the CY 2020 Hospital Price Transparency final rule (84 FR 65588 and 65589), we noted that commenters tended to be divided between those in favor of lower and higher CMP amounts, which indicated to us that the proposed (and subsequently finalized) $300 per day amount struck an appropriate balance between commenter concerns. We also noted that this $300 maximum daily dollar CMP amount is lower than CMPs imposed under certain other authorities administered by HHS agencies, where an entity's noncompliance poses immediate jeopardy, results in actual harm, or both, and stated our belief that the relatively lower amount for a CMP associated with a hospital's noncompliance with requirements to make public standard charges was reasonable since such noncompliance is less serious than noncompliance that poses or results in harm to the public.

As discussed in the CY 2020 Hospital Price Transparency final rule (84 FR

65589), we considered commenters' concerns that some hospitals may prefer to forgo meeting the requirements of 45 CFR part 180 (for example, to not expend resources on reporting or to protect pricing information they consider sensitive), and, instead, face compliance actions including a $300 maximum daily CMP amount. Although we declined at the time to increase the amount of the CMP based on this concern alone, we indicated that as we gained experience with implementing the policy we intended to monitor for such occurrences, and may revisit the need to adjust the amount of the CMP in future rulemaking.

We also considered the feasibility of implementing a sliding scale CMP approach across institutions that meet the definition of hospital according to § 180.20 (84 FR 65588 and 65589). However, at the time, we believed it would be challenging to find a reliable source of data that provides for a scalable factor across all institutions that meet the definition of hospital. Therefore, we declined the commenters' suggestions to scale the CMP amount based on such factors as hospital bed size, location or patient volume. However, we indicated that we would continue to consider this issue and might revisit use of a CMP scaling methodology in future rulemaking.

Based on our initial months of experience with enforcing the hospital price transparency requirements in 45 CFR part 180, we are concerned by what appears to be a trend towards a high rate of hospital noncompliance identified by CMS through sampling and reviews to date, and the reported initial high rate of hospital noncompliance with 45 CFR part 180 reflected in early studies.[410] [411] [412] [413] [414] [415] One approach we considered to address this trend is to amend the regulations to impose potentially higher CMPs for noncompliance with the hospital price transparency requirements, and to scale the CMP to ensure the penalty amount would be more relevant to the characteristics of the noncompliant hospital. We believe that CMPs are an important component in holding hospitals accountable for their noncompliance with hospital price transparency requirements, and signal the Secretary's continued support for public access to pricing information and enforcement.

Therefore, we considered two general approaches for increasing the CMP amount: (1) Use a flat increase in the amount that would be applied uniformly across all hospitals, for example, increasing the maximum CMP amount from $300 per day per hospital to $1,000 per day per hospital, or (2) establish a minimum penalty amount and apply a scaling factor (such as bed count or hospital revenue) to increase the penalty in a manner uniquely tailored to the noncompliant hospital. After considering these two general approaches, we propose to use a scaling factor to establish the CMP amount for a noncompliant hospital.

Several factors informed our proposal to use a scaling factor to determine the CMP amount for noncompliance with hospital price transparency requirements. First, this would allow us to penalize a hospital on a sliding scale in a manner that generally correlates to the hospital's characteristics, such as using the hospital's number of beds as a proxy for the size of the patient population it serves. Second, in the previous rulemaking, commenters suggested using a scaling factor as an alternative to a uniform CMP amount so as to not overly penalize smaller hospitals, while also providing a sufficient incentive for hospitals to comply. Third, other Federal programs use scaling factors in determining a CMP amount, in particular by taking into consideration the size of the entity subject to the penalty, or calculating the penalty based on the number of enrollees affected.[416] Fourth, since finalization of the CY 2020 Hospital Price Transparency final rule, we have had the opportunity to evaluate and determine a reliable source of data that could be used to establish a CMP amount across most institutions that meet the definition of 'hospital' as defined at § 180.20.

We also considered the potential specific scaling factor or factors that could be used, and an appropriate data source. We considered two options for a scaling factor: Hospital bed count and hospital revenue. We are proposing to use the noncompliant hospital's number of beds, as specified in hospital cost report data submitted to CMS, as the scaling factor to establish CMP amounts. We note that for purposes of this discussion, we consider ''number of beds'' to be synonymous with ''bed count,'' and we use the terms interchangeably.

We believe the hospital cost report data would be an appropriate data source for a scaling factor for the CMP amount because it is routinely submitted by Medicare-enrolled hospitals, is certified by a hospital official, and is reviewed by a Medicare Administrative Contractor (MAC) to determine acceptability. As explained on the *CMS.gov* website, Cost Reports web page, Medicare-certified institutional providers are required to submit an annual cost report to a MAC. The cost report contains provider information such as facility characteristics and financial statement data. CMS maintains the cost report data in the Healthcare Provider Cost Reporting Information System (HCRIS). HCRIS includes subsystems for the Hospital Cost Report (CMS–2552–96 and CMS–2552–10), among others.[417] Cost Report form CMS–2552–10 and related instructions are effective for

[410] Henderson M & Mouslim MC. Low Compliance From Big Hospitals On CMS's Hospital Price Transparency Rule. *Health Affairs.* March 16, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20210311.899634/full/.*

[411] Kennedy K, et al. The Insanity of U.S. Health Care Pricing: An Early Look at Hospital Price Transparency Data. *Health Care Cost Institute.* April 1, 2021. Available at: *https://healthcostinstitute.org/hcci-research/hospital-price-transparency-1.*

[412] Kurani N, et al. Early results from federal price transparency rule show difficulty in estimating the cost of care. *Peterson-KFF Health System Tracker.* April 9, 2021. Available at: *https://www.healthsystemtracker.org/brief/early-results-from-federal-price-transparency-rule-show-difficultly-in-estimating-the-cost-of-care/.*

[413] Severn C. The state of hospital price transparency, with pictures!. *Turquoise Health.* February 12, 2021. Available at: https://blog.turquoise.health/state-of-hospital-price-transparency-with-pictures/.

[414] Gondi S, et al. Early Hospital Compliance with Federal Requirements for Price Transparency. Research Letter. *JAMA Intern Medicine.* June 14, 2021. Available at: *doi:10.1001/jamainternmed.2021.2531.*

[415] Letter from Representatives Frank Pallone, Jr., Anna G. Eshoo, Cathy McMorris Rodgers & Brett Guthrie, to Secretary Xavier Becerra (April 13, 2021), available at *https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/HHS.2021.04.13.pdf.*

[416] See for example: 42 CFR 3.408(e), specifying factors considered in determining the amount of a civil money penalty include the financial condition of the respondent, including the size of the respondent (among other factors).

45 CFR 160.408(d), specifying factors considered in determining the amount of a civil money penalty include the financial condition of the covered entity or business associate, consideration of which may include but is not limited to the size of the covered entity or business associate (among other factors).

CMS, Civil Money Penalty Calculation Methodology, Revised, June 21, 2019. Available at: *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019CMPMethodology06212019.pdf* (Pursuant to 42 CFR 422.760(b)(1) and (2), 423.760(b)(1) and (2), 417.500(c), and 460.46, CMS determines if the penalty for a deficiency should be calculated on a per enrollee or per determination basis.).

42 CFR 1003.510 and 45 CFR 102.3, specifying penalty amounts that vary based on number of beds of the hospital; imposing higher penalties for a hospital that has 100 beds or more compared to a hospital that has less than 100 beds.

[417] *CMS.gov*, Cost Reports. Available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports.*

hospitals and hospital health care complexes with cost reporting periods beginning on or after May 1, 2010.[418]

For cost reporting purposes, Medicare requires submission of annual reports covering a 12-month period of operations based upon the provider's accounting year. There are also circumstances under which a provider may file a short period cost report for part of a year.[419] Further, there are several exceptions to full cost reporting, including: If a provider does not furnish any covered services to Medicare beneficiaries during a cost reporting period (42 CFR 413.24(g)); or if the provider has had low utilization of covered services by Medicare beneficiaries (as determined by the MAC) and has received correspondingly low interim payments for the cost reporting period (42 CFR 413.24(h)). If the provider fails to submit the cost report, the MAC imposes a penalty by suspending claims payments until the hospital submits the cost report.[420]

The chief financial officer or administrator of the provider certifies the content of the submitted cost report are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions.[421] The MAC reviews the cost report within 30 days of receipt of the provider's cost report to determine acceptability. If the cost report is considered unacceptable, the MAC returns the cost report with a letter explaining the reasons for the rejection. When a cost report is rejected, it is deemed an unacceptable submission and treated as if a report had never been filed.[422] Further, the MAC enters certain data on the hospital cost report into HCRIS, including the cost report status as either: As submitted; Settled without audit; Settled with audit; Reopened; or Amended.[423]

One of the facility characteristics contained in the cost report is ''number of beds,'' which is the number of beds available for use by patients at the end of the cost reporting period. Specifically, ''[a] bed means an adult bed, pediatric bed, portion of inpatient labor/delivery/postpartum (LDP) room (also referred to as birthing room) bed when used for services other than labor and delivery, or newborn ICU bed (excluding newborn bassinets) maintained in a patient care area for lodging patients in acute, long term, or domiciliary areas of the hospital. Beds in post-anesthesia, post-operative recovery rooms, outpatient areas, emergency rooms, ancillary departments (however, see exception for labor and delivery department), nurses' and other staff residences, and other such areas which are regularly maintained and utilized for only a portion of the stay of patients (primarily for special procedures or not for inpatient lodging) are not termed a bed for these purposes.'' [424]

For Medicare-enrolled hospitals, we propose to determine the CMP amount using the number of beds for the noncompliant hospital, as specified on the most recently available, finalized cost report data. We anticipate this would be the number of beds for the hospital as indicated in HCRIS as either Settled without audit, Settled with audit, Reopened, or Amended.

We propose the following approach to scaling the CMP amount based on the hospital's number of beds, and as summarized in Table 63:

- For a noncompliant hospital with a number of beds equal to or less than 30, the maximum daily dollar CMP amount would be $300, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.
- For a noncompliant hospital with a number of beds between 31 and 550, the maximum daily dollar CMP amount would be the number of beds times $10, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.
- For a noncompliant hospital with a number of beds greater than 550, the maximum daily dollar CMP amount would be $5,500, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180.

Therefore, for hospitals with 30 or fewer beds, the CMP amount under the proposed approach would be unchanged compared to the existing policy under § 180.90(c)(2). The proposed use of bed count as a scaling factor would increase the penalty, in some cases significantly, for larger hospitals. The following examples illustrate the proposed approach. A small noncompliant hospital with a bed count of fewer than 30 would be subject to the current CMP amount of $300/day or $109,500/year (that is, 365 days or a full CY of noncompliance). A noncompliant hospital with a bed count of 200 would be assessed a penalty of $2,000/day ($10*200/day) or $730,000/year. A noncompliant hospital with a bed count of 550 beds or more would be assessed a maximum penalty of $5,500/day ($10*550/day) or $2,007,500/year.

[418] CMS, The Provider Reimbursement Manual—Part 2, publication #15–2. Chapter 40, Hospital and Hospital Health Care Complex Cost Report Form CMS–2552–10. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, Chapter 40–(T16)—Hospital & Hospital Health Care (Form CMS–2552–10) (ZIP), file ''R16P240.pdf'' (herein The Provider Reimbursement Manual—Part 2, Chapter 40). Refer to section 4000, General, 40–7.

[419] CMS, The Provider Reimbursement Manual—Part 2, publication #15–2. Chapter 1, Cost Reporting—General. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, Chapter 1—Cost Reporting General (ZIP), file ''pr2_100_to_140.doc''. Refer to section 102, Cost Reporting Period, 1–3.

[420] 42 CFR 413.20(e). See also, CMS, Hospital and Hospital Health Care Complex Cost Report, CMS Form CMS–2552–10, dated 2020–11–10. Available at: *https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-2552-10*, CMS–2552–10.zip (ZIP), file ''CMS–2552–10_Supporting_Statement_Part_A.pdf'' (Payment/Gifts to Respondents).

[421] 42 CFR 413.24(f)(4)(iv). See also, Form CMS–2552–10. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, Chapter 40–(T16)—Hospital & Hospital Health Care (Form CMS–2552–10) (ZIP), file ''R16P240f.pdf'', Part II—Certification.

[422] 42 CFR 413.24(f)(5)(iii).

[423] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to Worksheet S—HOSPITAL AND HOSPITAL HEALTH CARE COMPLEX COST REPORT CERTIFICATION AND SETTLEMENT SUMMARY, section 4003.1, Part I—Cost Report Status, Line 5, column 1.

[424] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to Worksheet S–3—HOSPITAL AND HOSPITAL HEALTH CARE COMPLEX STATISTICAL DATA AND HOSPITAL WAGE INDEX INFORMATION, section 4005.1, Part 1—Hospital and Hospital Health Care Complex Statistical Data, Column 2.

TABLE 63: Proposed Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years.

Number of Beds	Penalty Applied Per Day	Total Penalty Amount for full Calendar Year of Noncompliance
30 or less	$300 per hospital	$109,500 per hospital
31 up to 550	$310 - $5,500 per hospital (number of beds times $10)	$113,150 - $2,007,500 per hospital
>550	$5,500 per hospital	$2,007,500 per hospital

Note: In subsequent years, amounts adjusted according to 45 CFR 180.90(c)(3).

We reviewed CMP amounts for other HHS programs that require reporting information and we believe our proposed maximum daily dollar penalty amount on a sliding scale between $300 and $5,500 per day per hospital is commensurate with the level of severity of the potential violation, taking into consideration that nondisclosure of standard charges does not rise to the level of harm to the public as other violations (such as safety and quality issues) for which HHS imposes CMPs and, therefore, should remain at a relatively lower level. For instance, the proposed maximum amount of $5,500/day, totaling $2,007,500/year would generally align with amounts used by other HHS initiatives that impose CMPs, such as HIPAA-related CMPs that, pursuant to statute, cap penalties at $1.5 million annually.[425]

We propose that if the number of beds for the hospital cannot be determined according to the most recently available, finalized Medicare cost report data in HCRIS, CMS would use documentation provided by the hospital to determine the number of beds for purposes of calculating the CMP. This approach would be needed to determine the number of beds for a hospital that is not Medicare-enrolled and therefore does not submit to CMS a hospital cost report. Further, we believe there could be circumstances under which there may be an apparent discrepancy, or obvious error, in the most recently available, finalized cost report data for a hospital within HCRIS, and additional documentation from the hospital would be needed to accurately determine the CMP amount.

In the event that CMS requires additional documentation to determine the CMP amount, we propose to require that the hospital provide CMS with documentation of its number of beds, in a form and manner and by the deadline prescribed by CMS in a written notice provided to the hospital. Should a hospital fail to provide CMS with this documentation, in the prescribed form and manner and by the specified deadline, we propose that we would impose a CMP on the hospital at the highest, maximum daily dollar amount within the proposed sliding scale. For example, under the proposed approach, if CMS cannot determine a noncompliant hospital's number of beds using hospital cost report data in HCRIS, and if the noncompliant hospital fails to provide CMS with documentation of its number of beds, in the form and manner and by the deadline specified by CMS, we would impose a CMP calculated based on a number of beds greater than 550, and therefore we would impose the maximum penalty of $5,500/day ($10*550/day) or $2,007,500/year.

Additionally, we propose that the approach for scaling the CMP amount based on the hospital's number of beds would apply to days the hospital is out of compliance with hospital price transparency requirements beginning with the effective date of the final rule, assuming the rule is finalized as proposed, and which we anticipate would be January 1, 2022. Further, according to § 180.90(c)(3), the amount of the CMP will be adjusted annually using the multiplier determined by OMB for annually adjusting CMP amounts under 45 CFR part 102. As described in the CY 2020 Hospital Price Transparency final rule (84 FR 65586), this multiplier is based on the Consumer Price Index for All Urban Consumers (CPI–U), not seasonally adjusted. Given that the requirements in 45 CFR part 180, as established by the CY 2020 Hospital Price Transparency final rule, were effective January 1, 2021, and because of the proposed effective date of January 1, 2022, for the modifications to the CMP amounts in this proposed rule, we would apply the cost-of-living adjustment multiplier determined by OMB, in calculating CMP amounts for hospital noncompliance with the requirements in 45 CFR part 180, beginning in CY 2023 and subsequent years.

To assist the public in considering the proposals to determine the CMP amount based on the most recently available, finalized number of beds for a hospital indicated in HCRIS, we note that CMS makes public hospital cost report data in several resources. Data files by fiscal year are accessible through the Cost Reports by Fiscal Year web page, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year*. Specifically, refer to data files by fiscal year (through FY 2020, at the time of this proposed rule) for facility type ''HOSPITAL–2010.'' Further, a subset of hospital cost report data for 2014 through 2017 is also made public through the Hospital Cost Report Public Use File web page, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Cost-Report/HospitalCostPUF* (providing access to data as either an Interactive Dataset or a Downloadable Excel file).

We seek comment on the proposal to use a sliding scale approach, based on the hospital's number of beds, to determine the CMP amount. In particular, we seek comment on specifying a minimum penalty amount of $300, consistent with the existing CMP amount, for hospitals with 30 beds or fewer, and whether 30 beds is an appropriate number to delineate for this part of the scale. We seek comment on the proposal to impose a CMP of $10/bed/day on hospitals with 31 beds up to 550 beds, including whether we should specify a higher amount to ensure hospitals' compliance with the requirements to make public standard charges. We seek comment on establishing a maximum daily penalty amount of $5,500 for hospitals with more than 550 beds. We also seek comment on our proposal to use hospital cost report data, as specified in HCRIS, to determine bed count, or if we

[425] *See* section 1176(a)(3) of the Social Security Act; 45 CFR 160.404.

should consider using other validated data sources or files. In particular, we are interested in commenters' input on whether there are any available data sources that would encompass relevant scaling data for all hospitals that are subject to the regulations at 45 CFR part 180, including hospitals that are not Medicare-enrolled.

As an alternative approach, we considered using hospital revenue as a scaling factor, instead of or in addition to hospital bed count, as it could more directly take into account the financial burden that a CMP might impose on a noncompliant hospital. For example, we considered using hospital cost report data to determine the noncompliant hospital's annual ''net patient revenues,'' [426] and to calculate a CMP amount as 0.1 percent of hospital revenue, prorated based on the number of days the hospital is out of compliance. That is, we would multiply the revenue amount by 0.001, and then divide the resulting product by 365 to determine the daily CMP amount. Under this alternative approach to scaling the CMP amount based on hospital revenue, as summarized in Table 64, the minimum penalty applied would remain $300 per day up to a maximum penalty of approximately $5,480 per day, which would continue to generally align with CMPs for issues unrelated to harm to the public. Were we to adopt an approach for using hospital revenue to scale the CMP amount, we would need to address with greater specificity additional factors, including the amount of precision used in the calculations, such as whole dollar amounts, or two decimal place precision.

TABLE 64: Proposed Alternative Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years.

Net Patient Revenues	Penalty Applied Per Day	Total Penalty Amount for full Calendar Year of Noncompliance
$109,500,000 or less	$300 per hospital	$109,500 per hospital
>$109,500,000 up to $2,000,000,000	$300 - $5,479 per hospital (0.1% of revenue prorated by day)	$109,500 - $1,999,835 per hospital
>$2,000,000,000	$5,480 per hospital	$2,000,200 per hospital

Note: In subsequent years, amounts adjusted according to 45 CFR 180.90(c)(3).

However, we are concerned that an approach that uses hospital revenue as a scaling factor for determining the CMP amount may not be as effective as a scaling factor based on bed count in targeting penalties to the size of the hospital. As indicated previously, current evidence suggests that noncompliance is fairly high among larger hospitals.[427] By failing to post the standard charge data, these hospitals are directly hindering consumers' decision-making ability. We believe that the larger the hospital size (as determined by bed count), the more potential patients are impacted, and that hospital bed count can serve as a more reliable proxy for the number of potential patients that the hospital serves than using net patient revenues. Conversely, application of a penalty based on net patient revenues would increase the penalty for better resourced hospitals compared to those that might have fewer resources. Such an approach may be more effective at deterring noncompliance among better resourced hospitals which may choose not to comply with the hospital price transparency requirements when the financial benefit of noncompliance outweighs a relatively low CMP amount.

In addition to bed size and hospital revenue, we also considered whether and how we could use additional scaling factors for assessing CMPs such as:

- Other financial metrics for scaling the CMP amount, such as using gross revenue, inpatient, or outpatient revenue to establish a penalty amount.
- The nature, scope, severity, and duration of the noncompliance. For example, taking into account the nature and number of deficiencies found upon review, in addition to applying penalties based on the number of days out of compliance.
- The hospital's reason for noncompliance. For example, applying a greater penalty for intentional noncompliance, such as if a hospital states its willful noncompliance on its website or in response to a compliance action from CMS, or application of a lesser penalty that takes into account extreme and uncontrollable circumstances.

While using multiple scaling factors might have advantages, such as being able to tailor the amount of the CMP to account for unique hospital circumstances and the potential to assess a greater CMP for egregious noncompliance, we are not proposing it at this time because we would need additional time and input to ensure that such scaling factors could be applied in a consistent manner across all hospitals that are subject to these regulations. However, we believe such refinements could improve our application of CMPs to promote hospital compliance and therefore seek comment on the following:

- What additional factors would be feasible for scaling a CMP amount?
- What data sources for the criteria could be used to ensure consistency in application of the criteria across all hospitals subject to these regulations? For example, if hospital revenue was used to scale penalties, what data source to determine revenue should be used? For example, are gross income, net income, net patient revenues, or some other metric appropriate for determining burden imposed by a CMP?
- How should nature, scope, and severity of noncompliance be

[426] The Provider Reimbursement Manual—Part 2, Chapter 40. Refer to section 4040.4, Worksheet G–3—Statement of Revenues and Expenses, describing calculation of Net Patient Revenues (subtract Less: Allowance and Discounts on Patient's Accounts from Total Patient Revenue).

[427] Henderson M & Mouslim MC. Low Compliance From Big Hospitals On CMS's Hospital Price Transparency Rule. *Health Affairs*. March 16, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/hblog20210311.899634/full/*.

determined and applied for purposes of assessing CMPs?

• How should a hospital's reason for noncompliance be determined? What factors should be considered when evaluating reason for noncompliance? Are there bases for imposing lower CMPs, such as resource limitations or extreme or unusual circumstances? If yes, how could resource limitations or circumstances contributing to noncompliance be demonstrated and should that be treated differently than documented statements of intent to not comply with the requirements?

• If multiple factors are used to scale the CMP amount, should there be a priority applied to specific factors? Should some factors be weighted more when determining the CMP amount? If yes, which one(s)?

We propose to revise the regulations at 45 CFR 180.90(c)(2) to specify an amended approach for determining the daily dollar amount for a CMP CMS may impose upon a hospital for noncompliance with the requirements in 45 CFR part 180. As conforming changes, we propose to specify in the regulations at § 180.90(c)(2)(i), the existing approach to determining the CMP amount, as not to exceed $300 per day, with introductory text specifying the provision is applicable for CY 2021. We propose to specify in the regulations at § 180.90(c)(2)(ii), provisions for determining the CMP amount for each day a hospital is determined by CMS to be out of compliance beginning January 1, 2022. The CMP amount would be based on the hospitals' number of beds: (A) A maximum daily dollar CMP amount of $300 for hospitals with a number of beds equal to or less than 30; (B) a maximum daily dollar CMP amount calculated as number of beds times $10 for hospitals with a number of beds between 31 and 550; and (C) a maximum daily dollar CMP amount of $5,500 for hospitals with a number of beds greater than 550. We also propose to specify within § 180.90(c)(2)(ii)(D)(*1*) that CMS would determine the number of beds for a Medicare-enrolled hospital using the most recently available, finalized Medicare hospital cost report. We also propose to specify within § 180.90(c)(2)(ii)(D)(*2*) the process by which CMS would determine the hospital's number of beds if such information could not be determined using Medicare hospital cost report data. We specify the conditions for CMS' receipt of documentation from the hospital to determine its number of beds, and specify that if the hospital does not provide CMS with such documentation (in the prescribed form and manner, and by the specified deadline), CMS would impose a CMP on the hospital at the highest, maximum daily dollar amount ($5,500 per day). We welcome comments on these proposals, and the alternatives we considered.

C. Proposal To Deem Certain State Forensic Hospitals as Having Met Requirements

Section 180.30(b) of our regulations states that the hospital price transparency requirements at 45 CFR part 180 are not applicable to federally-owned or operated hospitals, including hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act, and federally owned hospital facilities such as facilities operated by the U.S. Department of Veterans Affairs and Military Treatment Facilities (MTFs) operated by the U.S. Department of Defense. As we explained in the CY 2020 Hospital Price Transparency final rule, we concluded that these exceptions were appropriate because, with the exception of some emergency services, these facilities do not provide services to the general public and their established payment rates for services are not subject to negotiation. Instead, each of these facility types is authorized to provide services to specific populations that meet specific eligibility criteria (84 FR 65532). In addition, federally-owned or operated hospitals such as Indian Health Service and Tribal facilities [428] impose no cost-sharing, or, in the case of VA hospitals [429] and Department of Defense MTFs,[430] little cost-sharing. With respect to such facilities where there is cost-sharing, the charges are publicized through the **Federal Register**, Federal websites, or direct communication and therefore known to the populations served by such facilities in advance of receiving health care services. Only emergency services, which would not be shoppable services under our definition because they cannot be scheduled in advance, are available to otherwise non-eligible individuals at federally-owned or operated facilities. Because these hospitals do not treat the general public and their rates are not subject to negotiation, we concluded that it was appropriate to establish different requirements that apply to these hospitals.

Following publication of the final rule, we became aware that some state psychiatric facilities, specifically, state forensic hospitals, may be similarly situated to the types of facilities to which the exception in § 180.30(b) applies and should therefore also be deemed to be in compliance with 45 CFR part 180. Some state forensic facilities are public psychiatric hospitals that exclusively treat patients who are in the custody of penal authorities and who are not responsible for payment for the cost of their care in such facilities which are wholly funded through state general funds.[431] We believe it is reasonable to consider deeming such hospitals as having met the requirements of 45 CFR part 180 for similar reasons that we articulated in the CY 2020 Hospital Price Transparency final rule for deeming federally owned or operated facilities as having met these requirements. Specifically, such state forensic hospitals have specialized patient populations, are not open to the general public, and the rates for such hospital services are not negotiated. Therefore we are proposing to adopt this exception by modifying the introductory language in § 180.30(b) and adding new § 180.30(b)(3) to include state forensic hospitals. For purposes of application of this exception, we propose to add a definition to § 180.20 to define a ''state forensic hospital'' as a public psychiatric hospital that provides treatment for individuals who are in the custody of penal authorities.[432] Such forensic patients typically include: (1) Offenders incompetent to stand trial, (2) offenders with mental health disorders, (3) mentally ill prisoners transferred from prison, (4) offenders found not guilty by reason of insanity, or (5) post incarcerated civilly committed individuals.[433] In order to be deemed as having met requirements, the state forensic hospital must provide treatment exclusively for individuals who are in the custody of penal authorities (for example, a state

[428] Section 1680r(b) of the Indian Health Care Improvement Act (25 U.S.C. 1680r).

[429] VA cost-sharing information available at: *https://www.va.gov/HEALTHBENEFITS/cost/copays.asp*.

[430] MTF cost-sharing information available at: *https://tricare.mil/Costs/Compare* and *https://comptroller.defense.gov/Portals/45/documents/rates/fy2019/2019_ia.pdf*.

[431] Substance Abuse and Mental Health Services Administration, Controlled Expenditures and Revenues for Mental Health Services, State Fiscal Year 2009. Available at: *https://store.samhsa.gov/sites/default/files/d7/priv/sma14-4843.pdf*.

[432] CMS.gov, Psychiatric Hospitals, available at: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Certificationand Complianc/PsychHospitals*.

[433] National Association of State Mental Health Program Directors. Forensic Patients in State Psychiatric Hospitals: 1999–2016. August 2017. Available at: *https://nasmhpd.org/sites/default/files/TACPaper.10.Forensic-Patients-in-State-Hospitals_508C_v2.pdf*.

psychiatric hospital with a forensic wing would not meet criteria necessary to be deemed to be in compliance). We estimate there are approximately 111 such institutions that could meet the definition of hospital at § 180.20.[434] We propose to add this exception to § 180.30(b). We welcome comments on this proposal.

D. Proposals Prohibiting Additional Barriers To Accessing the Machine-Readable File

Section 2718(e) of the PHS Act requires hospitals to ''make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services.''

In the CY 2020 OPPS/ASC final rule (84 FR 65556), we explained that we reviewed how hospitals were implementing earlier guidelines for making public hospital chargemasters, which took effect on January 1, 2019, and we expressed concern that some charge information made public by hospitals may be difficult for the public to locate. For example, information may be difficult to locate if the public is required to click down several levels in order to find the information. We also expressed our concern about barriers that could inhibit the public's ability to access the information once located. For example, we indicated that we were aware that some hospitals require consumers to set up a username and password, or require consumers to submit various types of other information, including, but not limited to, their email address, in order to access the data. We expressed concern that these requirements might deter the public from accessing hospital charge information.

Accordingly, we proposed and finalized regulations that a hospital would have discretion to choose the internet location it uses to post its file containing the list of standard charges so long as the comprehensive machine-readable file is displayed on a publicly-available web page, it is displayed prominently and clearly identifies the hospital location with which the standard charges information is associated, and the standard charge data are easily accessible, without barriers, and the data can be digitally searched (84 FR 65561).

Specifically, § 180.50 requires a hospital to make public its standard charges in a single machine-readable file. Section 180.50(d)(1) of our regulations gives a hospital discretion to choose a website for purposes of making its standard charge information available to the public in the machine-readable file. Section 180.50(d)(2) through (5) set forth our accessibility requirements for this information, including that the standard charge information must be displayed prominently and clearly identify the hospital location with which it is associated; easily accessible, without barriers, including but not limited to being free of charge, without having to establish a user account or password, and without having to submit personal identifying information (PII); and contained in a digital file, within which the standard charge information is digitally searchable. For purposes of these requirements: (1) ''displayed prominently'' means that the value and purpose of the web page and its content is clearly communicated, there is no reliance on breadcrumbs to help with navigation, and the link to the standard charge file is visually distinguished on the web page; (2) ''easily accessible'' means that standard charge data are presented in a single machine-readable file that is searchable and that the standard charges file posted on a website can be accessed with the fewest number of clicks; and (3) ''without barriers'' means that the data can be accessed free of charge, users do not have to input information (such as their name, email address, or other PII) or register to access or use the standard charge data file. Additionally, both the machine-readable file and its contents must be digitally searchable.

As discussed in the CY 2020 Hospital Price Transparency final rule, we believe there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare coverage costs (84 FR 65526). For purposes of displaying all standard charges for all items and services in a comprehensive machine-readable file, we proposed and finalized requirements for the file format, the content of the data in the file, and how to ensure the public could easily access and find the file. We acknowledged that the machine-readable file would contain a large amount of data; however, we indicated that we believe that a single data file would be highly useable by the public because all the data would be in one place. By ensuring accessibility to all hospital standard charge data for all items and services, we stated these data would be available for use by the public in price transparency tools, to be integrated into EHRs for purposes of clinical decision-making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare.

In our experience, many publicly available web pages that are selected by hospitals to host the machine-readable file (or a link to the machine-readable file) are discoverable using simple internet searches (using key words such as the hospital name plus 'standard charges,' 'price,' or 'machine-readable file') or, for example, by navigating to the hospital's home page and clicking and searching through pages related to patient billing and financing. Because of the flexibility we allowed to hospitals to choose the internet location, we recognize and expect that there will be some variability in how hospitals choose to publicly display their machine-readable file and how quickly the file can be found by the public. However, as noted earlier, this flexibility afforded under the regulation so long as the hospital ensures that the machine-readable file is accessible ''without barriers,'' including that the file and its contents would be digitally searchable (84 FR 65561).

In some cases, it appears that hospitals have made standard charge data available online but embedded it in websites without any ability for users to easily or directly download a ''single machine-readable file.'' In other cases, hospitals have posted a link to a single machine-readable file but have, either intentionally or unintentionally, placed barriers that make it more challenging for the public find and access the file and its contents. Examples of such activities and practices include:

- Employing common methods that hinder the findability[435] of a web page that contains a link to the machine-readable file, such as through the use anti-automation tools such as form submission, or other technological devices that place a ''locked door'' in front of the content thereby making it difficult or impossible for search engines to identify the data. There have also been reports of hospitals using ''blocking codes'' such as use of NOINDEX and ''rel canonical'' tagging or disallow statements or removing the URL from the search index through the use of the webmaster tools URL removal service. These techniques prevent

[434] National Mental Health Services Survey (N–MHSS): 2019, Data On Mental Health Treatment Facilities. Substance Abuse and Mental Health Services Administration. 2020. Available at: *https://www.samhsa.gov/data/report/national-mental-health-services-survey-n-mhss-2019-data-mental-health-treatment-facilities. See Table 3.6.a.*

[435] Fishkin R. 12 Ways to Keep Your Content Hidden from the Search Engines. *Moz.* January 15, 2008. Available at: *https://moz.com/blog/12-ways-to-keep-your-content-hidden-from-the-search-engines.*

commonly used web search engines from caching web pages on which the link to machine-readable files reside.[436] These examples of tools and codes present barriers because they limit the public's ability to easily search for and find the web page that hosts a link to the machine-readable file.

• Employing common methods that prevent direct access to the file and its contents. For example, some hospitals implement anti-automation tools such as requiring users to pass tests proving they are human users prior to accessing the file, for example, the implementation of CAPTCHA and reCAPTCHA in web applications. CAPTCHA stands for ''Completely Automated Public Turing test to Tell Computers and Humans Apart.'' Common CAPTCHA and reCAPTCHA mechanisms may include distorted text inside images, where the user has to type the text or nine or sixteen square images, where the user has to identify the images that contain certain objects, such as vehicles, trees, or street signs. In other instances, some hospitals require the user to take additional actions upon clicking the link to the machine-readable file, prior to download. For example, pop-up windows that require the user to agree all terms and conditions in a legal disclaimer prior to permitting the machine-readable file and its contents to be downloaded. Such pop-up windows do not permit direct access to the file and its contents, and present a barrier.

• Developing file constructs and web forms that obscure access to the data in a single machine-readable file through the use of Application Programming Interfaces (APIs). For example, we have found APIs that use calls for data that will not return a complete data file, that do not provide supporting documentation on the use of the API to retrieve the file, and that do not allow a single query to return all data in a single machine-readable file. These APIs control access to the data in a way that prevents or conceals access to the entire data file. As such, these types of APIs present barriers to direct access to a 'single machine-readable file' and are therefore not permissible forms of APIs for use by a hospital.

Given this additional experience, we are proposing to amend the regulations by adding paragraph (d)(3)(iv) to § 180.50 to specify that the hospital must ensure that the standard charge information is easily accessible, without barriers, including, but not limited to, ensuring the information is accessible to automated searches and direct file downloads through a link posted on a publicly available website. We believe this additional requirement will ensure greater accessibility to the machine-readable file and its contents and would prohibit practices we have encountered in our compliance reviews, such as lack of a link for downloading a single machine-readable file, using ''blocking codes'' or CAPTCHA, and requiring the user to agreement to terms and conditions or submit other information prior to access.

We seek comment on whether stakeholders have identified additional barriers that we should prohibit. We note that the list of examples of barriers we have encountered in our reviews of hospital websites is not intended to be exhaustive, and that should we identify additional barriers that prevent automated searches or direct download of the machine-readable file, we may prohibit them via, as appropriate, guidance or future rulemaking.

Finally, we seek comment on whether there are specific criteria we should consider when evaluating whether a hospital has displayed the machine-readable file in a ''prominent manner.'' Files that are posted in a prominent manner can reduce public burden for searching and finding the files and ensure the public can easily find the machine-readable file and the information contained within it. When files are posted prominently, we can also more easily monitor and assess hospital compliance with the CY 2020 Hospital Price Transparency final rule. For example, we are considering establishing a more standardized approach for how hospitals would be required to make public the machine-readable file, in order to relieve the burden on the public and ensure files are found easily. One such method would be to require hospitals to post their machine-readable files using a CMS-specified URL, in addition to the CMS-specified naming convention. Another approach could be to require a standardized location for hospitals to post a link to the file from the hospital's homepage, thus limiting the public's search for such files to the homepage of the hospital and relieving burden on the public to spend time searching for the file. We seek comment on these methods for ensuring that the machine-readable files posted are prominently displayed and easily accessible.

E. Clarifications and Requests for Comment

1. Clarification of the Price Estimator Tool Option and Request for Comment on Considerations for Future Price Estimator Tool Policies

In the CY 2020 Hospital Price Transparency final rule, we finalized requirements for hospitals to make public payer-specific negotiated charges, discounted cash prices, the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge for 300 ''shoppable'' services that are displayed and packaged in a consumer-friendly manner. We were also persuaded by commenters' suggestions that hospitals offering online price estimator tools that meet certain requirements including providing real-time individualized out-of-pocket cost estimates adequately satisfy our aim that hospitals communicate their standard charges in a consumer-friendly manner, and therefore deemed these price estimator tools as meeting our requirements for making public standard charges for a limited set of shoppable services (84 FR 65579).

We therefore finalized a policy at § 180.60(a)(2) that a hospital may voluntarily offer an internet-based price estimator tool and thereby be deemed to have met our requirements to make public its standard charges for selected shoppable services in a consumer-friendly manner, so long as such a price estimator tool:

• Provides estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.

• Allows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.

• Is prominently displayed on the hospital's website and be accessible without charge and without having to register or establish a user account or password.

To satisfy our requirement at § 180.60(a)(2)(ii), a price estimator tool ''[a]llows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service''. Moreover, such a price estimator tool must be ''tailored to individuals' circumstances (whether an individual is paying out of pocket or using insurance) and provide real-time individualized out of pocket estimates

[436] McGinty T, et al. Hospitals Hide Pricing Data from Search Results. *The Wall Street Journal.* March 22, 2021. Available at: *https://www.wsj.com/articles/hospitals-hide-pricing-data-from-search-results-11616405402.*

that combines hospital standard charge information with the individual's benefit information directly from the insurer, or provide the self-pay amount.'' (84 FR 65578) We emphasize this because our reviews of hospital compliance have identified that some hospital price estimator tools do not tailor a single estimated amount based on the individual's circumstance, but, instead, provide estimated average amounts or ranges for the price of a shoppable service that appear to be generated based on a broad population of patients, including outliers. Others do not appear to combine hospital standard charges with the individual's benefit information directly from the insurer to create the estimate, but instead, appear to use information from prior reimbursements or require the user to input benefit information. Still others appear tailored to the individual, but indicate that the price is not what the hospital anticipates that the individual would be obligated to pay, even in the absence of unusual or unforeseeable circumstances. Hence they fail to satisfy our requirements at § 180.60(a)(2).

We note that under the CY 2020 Hospital Price Transparency final rule, hospitals are not required to offer online price estimator tools. However, when a hospital chooses to offer an online price estimator tool as an alternative to presenting their standard charge information in a consumer friendly format, we believe it is important for the hospital to select and offer a price estimator tool that provides a single dollar amount that is tailored to the individual seeking the estimate, taking the individual's circumstances into consideration when developing the estimate. Moreover, the estimate must reflect the amount the hospital anticipates will be paid by the individual for the shoppable service, absent unusual or unforeseeable circumstances. We also emphasize that nothing in this rule precludes a hospital from providing additional information that may be helpful to the consumer, such as a range of prices paid by a defined population of consumers for the item or service in the past, or informing the inquirer what circumstances could change the personalized estimate.

Beyond these current minimum requirements, we are considering whether we should add requirements for the use of an online price estimator tool as an alternative to making public the standard charges for shoppable services in a consumer-friendly format. We seek stakeholder input for future consideration related to the price estimator tool policies, including identifying best practices, common features, and solutions to overcoming common technical barriers, and specifically, seek input on:

- What best practices should online price estimator tools be expected to incorporate?
- Are there common data elements that should be included in the online price estimator tool to improve functionality and consumer-friendliness?
- What technical barriers exist to providing patients with accurate real-time out-of-pocket estimates using an online price estimator tool? How could such technical barriers be addressed?

2. Request for Comment on the Definition of 'Plain Language'

In the CY 2020 Hospital Price Transparency final rule, we finalized requirements for displaying shoppable services in a consumer-friendly manner (§ 180.60). At § 180.60(b), we finalized certain required data elements a hospital must include when displaying its standard charges for its list of shoppable services, the first of which is a 'plain-language' description of each shoppable service. We recommended, but did not require, that hospitals review and use the Federal plain language guidelines,[437] which have been developed to assist Federal agencies to write clearly so that users can find what they need and understand and use what they find. The Federal plain language guidelines inform readers how to write to focus an audience on what it wants to know and guide it through the information, and how to organize information and carefully choose words to avoid jargon and minimize abbreviations.

In our reviews of hospital compliance, we have noticed that not all hospitals appear to be using what could reasonably be considered 'plain language' to describe shoppable services. For example, some hospitals have used internal code descriptions from the comprehensive machine-readable file rather than translating those descriptions into terminology that consumers may readily understand. In our effort to ensure hospital compliance with the use of 'plain language,' we seek public comment on whether we should require specific plain language standards, and, if so, what those plain language standards should be.

3. Request for Comment on Identifying and Highlighting Hospital Exemplars

We are aware that some hospitals are not only fully complying with the hospital price transparency requirements we have adopted, but are also embracing and exemplifying the spirit of consumer price transparency. Moreover, identification of such hospitals may draw attention to developing best practices that other hospitals may choose to adopt, or that could be used to establish criteria for assessing hospital compliance in the future. We therefore seek public comment on potential ways that we could highlight such hospital practices, and are considering approaches that include:

- Opportunities to highlight hospitals that are in compliance with various aspects of the Hospital Price Transparency regulations through education and outreach materials.
- Opportunities to highlight exemplar hospitals on existing CMS websites, for example, the Hospital Price Transparency website, Care Compare, or other CMS websites.
- Publicizing the results of comprehensive compliance reviews on our website.
- Opportunities to collaborate with consumer organizations, health policy organizations, hospital accrediting organizations or others to develop a price transparency certification. Depending on how such a certification process would be structured, we might consider proposing future regulatory action to deem certified hospitals as being in compliance with our regulations.
- Opportunities for integrating price transparency questions into patient experience of care assessments and surveys or other methods for integrating into hospital quality measurement and value-based purchasing initiatives.

In considering ways we could hold out hospitals as exemplars for patient-centered price transparency, we are also seeking public input on the following:

- Should hospitals be recognized for patient-centered price transparency efforts? If yes, how should such hospitals be identified and by whom? What criteria should be used for assessing patient-centered price transparency efforts?
- What method or methods for highlighting exemplar hospitals would be most beneficial to consumers?
- Of the methods described above, what are the relative advantages or disadvantages of each?

4. Request for Comment on Improving Standardization of the Machine-Readable File

In the CY 2020 Hospital Price Transparency final rule, we expressed our concern that lack of uniformity in

[437] See Federal plain language guidelines, available at: *https://plainlanguage.gov/guidelines/*.

the way that hospitals display their standard charges leaves the public unable to meaningfully use, understand, and compare standard charge information across hospitals (84 FR 65556). We agreed with commenters that standardization in some form would be important to ensure high utility for users of the hospital standard charge information, and we therefore finalized certain requirements, such as the data elements and file formats, that would be standardized across hospitals.

We codified these requirements at new § 180.50(b) and indicated that we believed that the finalized data elements (which included, as applicable, the hospital's standard charges, a description of the item or service, and common billing and accounting code) would be necessary to ensure that the public can compare standard charges for similar or the same items and services provided by different hospitals.

Commenters provided many additional suggestions for how to standardize the standard charge information displayed by hospitals. At the time we declined to be more prescriptive in our approach, but we noted that we may revisit these requirements in future rulemaking should we find it is necessary to make improvements in the display and accessibility of hospital standard charge information for the public.

Since implementation of the final rule, early feedback from stakeholders, particularly from IT specialists, researchers, and others who seek to use the standard charge information that hospitals are now required to make public, have indicated that more standardization of the machine-readable file may be necessary to meet the goal of permitting comparisons of standard charges from one hospital to the next. We are therefore seeking comment on the following issues:

- What is the best practice for formatting data such as hospital standard charge data? Is there a specific data format that should be required to be used across all hospitals? Are there any barriers to requiring a specific format to be used by all hospitals when displaying standard charge information?
- Are there additional data elements that should be required for inclusion in the future in order to ensure standard charge data is comparable across hospitals? What one(s)? Is such data readily found in hospital systems? In what ways would inclusion of such data impact hospital burden?
- Are there any specific examples of hospital disclosures that represent best practice for meeting the requirements and goals of the CY 2020 Hospital Price Transparency final rule? We invite submissions of links to machine-readable files that the public would consider to represent a best practice.
- What other policies or incentives should CMS consider to improve standardization and comparability of these disclosures?
- What other policies should CMS consider to ensure the data posted by hospitals is accurate and complete, for example, ensuring that hospitals post all payer-specific negotiated charges for all payers and plans with which the hospital has a contract, as required by the regulations?

XX. Additional Hospital Inpatient Quality Reporting (IQR) Program Policies

A. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) and eCQM Reporting Requirements in the Hospital IQR Program—Request for Information

1. Hospital IQR Program Background

We refer readers to the following final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861);
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181);
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653);
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837);
- 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);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328, 38348);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509); and
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959).

We note this is not an exhaustive list of all prior rulemaking for the Hospital IQR Program. We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations, as well as the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25561 through 25601) for currently proposed program changes for the Hospital IQR Program.

In this request for information (RFI), we seek input regarding the Safe Use of Opioids—Concurrent Prescribing electronic clinical quality measure (eCQM) (NQF # 3316e) (hereinafter referred to as the ''Safe Use of Opioids eCQM'') as well as our previously finalized policy of requiring hospitals to report on the Safe Use of Opioids eCQM beginning with the CY 2022 reporting period/FY 2024 payment determination (84 FR 42503 through 42505). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459) where we adopted the Safe Use of Opioids eCQM into the Hospital IQR Program beginning with the CY 2021 reporting period/FY 2023 payment determination. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42503 through 42505) in which we finalized our policy requiring hospitals to report on the Safe Use of Opioids eCQM beginning in the CY 2022 reporting period. We also refer readers to the FY 2021 IPPS/LTCH PPS final rule in which we finalized reporting of the Safe Use of Opioids eCQM as one of the four required eCQMs beginning with the CY 2022 reporting period/FY 2024 payment determination (85 FR 58933 through 58939). Specifically, for the CY 2022 reporting period/FY 2024 payment determination, hospitals will be required to report three self-selected calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQMs. For the CY 2023 reporting period/FY 2025 payment determination and subsequent years hospitals will be required to report four calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQMs. The Safe Use of Opioids eCQM is scheduled to be submitted to the National Quality Forum (NQF) in 2022 for re-endorsement consideration as part of the measure maintenance process. The purpose of this RFI is to gather public input for potential measure updates as we prepare for NQF re-endorsement of the endorsed Safe Use of Opioids—Concurrent Prescribing eCQM and to potentially inform any future rulemaking regarding this measure. We provide more detail on both the Safe Use of Opioids eCQM and the eCQM reporting requirements below.

2. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e)

a. Overview

The Safe Use of Opioids eCQM seeks to reduce preventable mortality and the costs of adverse events associated with opioid use by encouraging providers to identify patients who have concurrent prescriptions for opioids, or opioids and

benzodiazepines, and discouraging providers from prescribing these drugs concurrently, unless medically necessary or appropriate. This measure is intended to support a patient-centric approach to help identify and monitor patients at risk, and ultimately reduce the risk of harm to patients across the continuum of care. Specifically, the measure encourages providers to identify patients on medication combinations that could lead to adverse drug events at discharge and motivates providers to consider whether reevaluation of the current medication regimen is warranted. This measure ultimately seeks to help combat the opioid crisis, which has been declared a public health emergency and is recognized as a priority focus area for measurement by CMS and HHS. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459) where we adopted the Safe Use of Opioids eCQM into the Hospital IQR Program beginning with the CY 2021 reporting period/FY 2023 payment determination.

The Safe Use of Opioids eCQM assesses the proportion of inpatient hospitalizations for patients 18 years of age and older prescribed, or continued on, two or more opioids or an opioid and benzodiazepine concurrently at discharge. The numerator is comprised of patients whose discharge medications include two or more active opioids or an active opioid and benzodiazepine resulting in concurrent therapy at discharge from the hospital-based encounter (84 FR 42452). The denominator consists of patients who have inpatient hospitalizations (inpatient stay less than or equal to 120 days) that end during the measurement period, where the patient is 18 years of age and older at the start of the encounter, and is prescribed a new or continuing opioid or benzodiazepine at discharge (84 FR 42452). Patients who have cancer or are receiving palliative care would be excluded from the denominator (84 FR 42452).

A lower percentage for the measure indicates fewer concurrent prescriptions written. We emphasize that the Safe Use of Opioids eCQM is not expected to have a measure rate of zero (84 FR 42456). Clinician judgment, clinical appropriateness, or both may indicate that concurrent prescribing of two unique opioids, or an opioid and a benzodiazepine is medically necessary. For example, patients who are on medication for opioid use disorder (OUD) would be included in the measure denominator if they continue that active prescription at discharge and would be counted in the numerator if they receive another prescription for an opioid or benzodiazepine (84 FR 42452). We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58939) for more details on the Safe Use of Opioids eCQM.

b. Prior Stakeholder Feedback

We monitor and evaluate quality measures after they are adopted and implemented into the Hospital IQR Program measure set. We also engage with stakeholders through education and outreach opportunities, which include webinars and help desk questions submitted through the Office of the National Coordinator for Health Information Technology (ONC) Project Tracking System (JIRA) eCQM issue tracker for eCQM implementation and maintenance (84 FR 42454).

Since adopting the Safe Use of Opioids eCQM in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42459), stakeholders have expressed concern about potential unintended consequences associated with requiring reporting on the measure. Specifically, these stakeholders have noted their concern that requiring reporting on the Safe Use of Opioids eCQM could disincentivize clinicians from appropriately concurrently prescribing medications for the treatment of OUD, such as methadone and buprenorphine. They believe that if hospitals are required to report on this measure, clinicians might alter their prescribing practices, making it more difficult for patients to access appropriate treatment for OUD, and ultimately leading to patient harm in a vulnerable population.

We note that during measure development, clinicians from our expert panel considered single-condition exclusions such as OUD. After reviewing test results, they recommended continuing to include patients for whom concurrent prescribing is medically necessary, because they stated that those populations: (1) Have the highest risk of receiving concurrent prescriptions; (2) can experience a lag in adverse events; and (3) can experience adverse drug events if an overlap with benzodiazepines occurs (84 FR 42450 through 42451). As we previously noted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42456), the Safe Use of Opioids eCQM is not expected to have a measure rate of zero; however, this is an important topic and a particular focus area of our monitoring efforts as the eCQM data start to be submitted and on which we are currently seeking comment, as further discussed below.

c. National Quality Forum Re-Endorsement

The Safe Use of Opioids eCQM is scheduled to be submitted to the NQF in 2022 for re-endorsement. In support of that effort, our measure development contractor plans to conduct additional testing, which will include substance use disorder treatment and sickle cell disease. Testing will include discussions with the technical expert panel to identify any potential updates to test as well as testing the rate of concurrent morphine/buprenorphine prescribing alongside opioids and benzodiazepines. Testing work will also include recruiting test sites, receiving test site data, reassessing validity, reliability, performance scores, exclusions, and performance gaps. This testing could be used to inform possible future measure updates or exclusions.

3. Current eCQM Reporting and Submission Requirements for the Hospital IQR Program

Beginning with the CY 2021 reporting period/FY 2023 payment determination, the Safe Use of Opioids eCQM was added as part of the eCQM measure set as one of the eCQMs that eligible hospitals can choose from to meet the eCQM reporting requirements for the Hospital IQR and Medicare Promoting Interoperability Programs (84 FR 42449 through 42459 and 84 FR 42598 through 42599, respectively). Beginning with the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to report data for each required eCQM: (a) Three self-selected eCQMs from the set of available eCQMs for CY 2022, and (b) the Safe Use of Opioids eCQM (85 FR 58933 through 58939). We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58939) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42506) for more detailed discussions of the current eCQM reporting and submission requirements for the Hospital IQR Program.

4. Solicitation of Comments

In this RFI, we seek public input on the following:

- *Potential future measure updates of the Safe Use of Opioids eCQM.* We seek additional information or considerations to inform future measure updates to the Safe Use of Opioids eCQM.
- *Required Reporting and Submission Requirement for the Safe Use of Opioids eCQM.* Currently, hospitals are required to report: (a) Three self-selected eCQMs from the set of available eCQMs, and (b)

the Safe Use of Opioid eCQM for the CY 2022 reporting period/FY 2024 and subsequent years. As we consider future reporting on the Safe Use of Opioids eCQM, we seek comments on the appropriateness of maintaining this previously finalized policy or allowing hospitals to self-select the Safe Use of Opioids eCQM from our finalized set of eCQMs.

XXI. Additional Medicare Promoting Interoperability Program Policies

A. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) and eCQM Reporting Requirements in the Medicare Promoting Interoperability Program—Request for Information

1. Medicare Promoting Interoperability Program Background

We refer readers to the following final rules for detailed discussions regarding the history of the Medicare Promoting Interoperability Program (previously known as part of the Medicare and Medicaid Electronic Health Record Incentive Programs):

- The Electronic Health Record Incentive Program Stage 1 final rule (75 FR 44314);
- The Electronic Health Record Incentive Program Stage 2 final rule (77 FR 53968);
- The Electronic Health Record Incentive Program Stage 3 final rule (80 FR 62762);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 25245 through 25247);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38487 through 38493);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41634 through 41677);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42591 through 42602); and
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58966 through 58977).

We note this is not an exhaustive list of all prior rulemaking for the Medicare Promoting Interoperability Program. We also refer readers to 42 CFR part 495 for the Medicare Promoting Interoperability Program regulations, as well as the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25628 through 25654) for proposed changes to the Medicare Promoting Interoperability Program.

In this request for information (RFI), to maintain alignment with the Hospital Inpatient Quality Reporting Program, we seek input regarding the Safe Use of Opioids—Concurrent Prescribing electronic clinical quality measure (eCQM) (NQF #3316e) (hereinafter referred to as the ''Safe Use of Opioids eCQM'') as well as our previously finalized policy of requiring hospitals to report on the Safe Use of Opioids eCQM beginning with the CY 2022 reporting period (84 FR 42598 through 42600 and 85 FR 58970 through 58975). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42599) where we adopted the Safe Use of Opioids eCQM into the Medicare Promoting Interoperability Program beginning with the CY 2021 reporting period, as we continued to align with the Hospital IQR Program. We also refer readers to the FY 2020 and FY 2021 IPPS/LTCH PPS final rules (84 FR 42597 through 42600 and 85 FR 58970 through 58975 respectively) in which we finalized our policy requiring hospitals to report on the Safe Use of Opioids eCQM beginning with CY 2022 reporting period. The Safe Use of Opioids eCQM is scheduled to be submitted to the National Quality Forum (NQF) in 2022 as part of the measure maintenance process. The purpose of this RFI is to gather public input for potential measure updates as we prepare for NQF re-endorsement of the endorsed Safe Use of Opioids—Concurrent Prescribing eCQM and to potentially inform any future rulemaking regarding this measure. We provide more detail on both the Safe Use of Opioids eCQM and the eCQM reporting requirements in section XX.A.3.

2. Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e)

a. Overview

The Safe Use of Opioids eCQM seeks to reduce preventable mortality and the costs of adverse events associated with opioid use by encouraging providers to identify patients who have concurrent prescriptions for opioids, or opioids and benzodiazepines, and discouraging providers from prescribing these drugs concurrently, unless medically necessary or appropriate. This measure is intended to support a patient-centric approach to help identify and monitor patients at risk, and ultimately reduce the risk of harm to patients across the continuum of care. Specifically, the measure encourages providers to identify patients on medication combinations that could lead to adverse drug events at discharge and motivates providers to consider whether reevaluation of the current medication regimen is warranted. This measure ultimately seeks to help combat the opioid crisis, which has been declared a public health emergency and is recognized as a priority focus area for measurement by CMS and HHS.

The Safe Use of Opioids eCQM assesses the proportion of inpatient hospitalizations for patients 18 years of age and older prescribed, or continued on, two or more opioids or an opioid and benzodiazepine concurrently at discharge. The numerator is comprised of patients whose discharge medications include two or more active opioids or an active opioid and benzodiazepine resulting in concurrent therapy at discharge from the hospital-based encounter. The denominator consists of patients who have inpatient hospitalizations (inpatient stay less than or equal to 120 days) that end during the measurement period, where the patient is 18 years of age and older at the start of the encounter, and is prescribed a new or continuing opioid or benzodiazepine at discharge. Patients who have cancer or are receiving palliative care would be excluded from the denominator (84 FR 42452).

A lower percentage for the measure indicates fewer concurrent prescriptions written. We emphasize that the Safe Use of Opioids eCQM is not expected to have a measure rate of zero (84 FR 42456). Clinician judgment, clinical appropriateness, or both may indicate that concurrent prescribing of two unique opioids, or an opioid and a benzodiazepine is medically necessary. Patients who are on medication for opioid use disorder (OUD) would be included in the measure denominator if they continue that active prescription at discharge and would be counted in the numerator if they receive another prescription for an opioid or benzodiazepine (84 FR 42452). We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42599) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58939) for more details on the Safe Use of Opioids eCQM.

b. Prior Stakeholder Feedback

We monitor and evaluate quality measures after they are adopted and implemented into the Medicare Promoting Interoperability Program measure set. In collaboration with the Hospital IQR Program, we engage with stakeholders through education and outreach opportunities, which include webinars and help desk questions submitted through the Office of the National Coordinator for Health Information Technology (ONC) Project Tracking System (JIRA) eCQM issue tracker for eCQM implementation and maintenance (84 FR 42454).

Since adopting the Safe Use of Opioids eCQM in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42599), stakeholders have expressed concern about the potential unintended consequences associated with requiring reporting on the measure. Specifically, these stakeholders have

noted their concern that requiring reporting on the Safe Use of Opioids eCQM could disincentivize clinicians from appropriately concurrently prescribing medications for the treatment of OUD, such as methadone and buprenorphine. They believe that if hospitals are required to report on this measure, clinicians might alter their prescribing practices, making it more difficult for patients to access appropriate treatment for OUD, and ultimately leading to patient harm in a vulnerable population.

We note that during measure development, clinicians from our expert panel considered single-condition exclusions such as OUD. After reviewing test results, they recommended continuing to include patients for whom concurrent prescribing is medically necessary, because they stated that those populations: (1) Have the highest risk of receiving concurrent prescriptions; (2) can experience a lag in adverse events; and (3) can experience adverse drug events if an overlap with benzodiazepines occurs (84 FR 42450 through 42451). As was explained by the Hospital IQR Program in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42456), the Safe Use of Opioids eCQM is not expected to have a measure rate of zero; however, this is an important topic and a particular focus area of our monitoring efforts as the eCQM data start to be submitted and on which we are currently seeking public comments, as further discussed in section XX.A.4.

c. National Quality Forum Re-Endorsement

The Safe Use of Opioids eCQM is scheduled to be submitted to the NQF in 2022 for re-endorsement. In support of that effort, our measure development contractor plans to conduct additional testing, which will include substance use disorder treatment and sickle cell disease. Testing will include discussions with the technical expert panel to inform potential updates to test as well as testing the rate of concurrent morphine/buprenorphine prescribing alongside opioids and benzodiazepines. Testing work will also include recruiting test sites, receiving test site data, reassessing validity, reliability, performance scores, exclusions, and performance gaps. This testing could be used to inform possible future measure updates or exclusions.

3. Current eCQM Reporting and Submission Requirements for the Medicare Promoting Interoperability Program

Previously finalized Medicare Promoting Interoperability Program policy for the CY 2022 reporting period requires eligible hospitals and CAHs to report three self-selected calendar quarters of data for each required eCQM: (a) Three self- selected eCQMs from the set of available eCQMs for CY 2022, and (b) the Safe Use of Opioids eCQM, for a total of four eCQMs (85 FR 58970 through 58975). We finalized the requirement that hospitals report on the Safe Use of Opioids eCQM in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42600) such that the Medicare Promoting Interoperability Program was in direct alignment with finalized proposals in the Hospital IQR Program.

Beginning with the CY 2021 reporting period, the Safe Use of Opioids eCQM was added as part of the eCQM measure set as one of the eCQMs that eligible hospitals can choose from to meet the eCQM reporting requirements for the Hospital Inpatient Quality Reporting Program and Medicare Promoting Interoperability Program (84 FR 42449 through 42459 and 84 FR 42598 through 42599, respectively). We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58970 through 58975) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42598 through 42600) for more detailed discussions of the current eCQM reporting and submission requirements for the Medicare Promoting Interoperability Program.

4. Solicitation of Comments

For this RFI, in alignment with a similar RFI pertaining to the Hospital IQR Program, we seek public input on the following:

- *Potential future measure updates of the Safe Use of Opioids eCQM.* We seek additional information or considerations to inform future measure updates of the Safe Use of Opioids eCQM;
- *Required Reporting and Submission Requirement for the Safe Use of Opioids eCQM.* Currently eligible hospitals and CAHs are required to report (a) Three self-selected eCQMs from the set of available eCQMs, and (b) the Safe Use of Opioid eCQM for the CY 2022 reporting period and subsequent years. As we consider future reporting on the Safe Use of Opioids eCQM, we seek comments on the appropriateness of maintaining this previously finalized policy or allowing hospitals to self-select the Safe Use of Opioids eCQM from our finalized set of eCQMs (which includes the Safe Use of Opioids eCQM) for the CY 2022 reporting period and subsequent years.

XXII. 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 final rule with comment period (83 FR 59154), for CY 2019, we changed 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 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). For CY 2022, we are proposing to retain these columns, updated to reflect the amount of the 2022 inpatient deductible. In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS addenda A, B, and C by adding a new column to the OPPS addenda, A, B, and C, entitled ''Drug Pass-Through Expiration during Calendar Year'' where we flagged through the use of an asterisk, each drug for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2022, we are proposing to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in CY 2022.

To view the Addenda to this proposed rule pertaining to proposed CY 2022 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 ''CMS–1753–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled ''2022 NPRM OPPS Addenda'' in the related links section at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2022 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 ''CMS–1753–P'' from the list of regulations. The ASC Addenda to this

proposed rule are contained in a zipped folder entitled ''Addendum AA, BB, DD1, DD2, and EE.'' in the related links section at the bottom of the page.

XXIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), 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.

We are soliciting 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 Outpatient Quality Reporting (OQR) Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the CY 2011 through CY 2021 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; 82 FR 59476 through 59479; 83 FR 59155 through 59156; 84 FR 61468 through 61469; and 85 FR 86266 through 86267, respectively) for detailed discussions of the previously finalized Hospital OQR Program ICRs. The ICRs associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109, which expires on March 31, 2023. We continue to estimate a total of 3,300 hospitals will submit required measure data for the Hospital OQR Program, unless otherwise noted. While the exact number of hospitals required to submit data annually may vary, we use this estimate to be consistent with previous rules and for ease of calculation across reporting periods.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52617), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the Hospital OQR Program. The latest data from the BLS' May 2020 Occupational Employment and Wages data reflects a median hourly wage of $21.20 per hour for a Medical Records and Health Information Technician professional.[438] We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52617). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($21.20 × 2 = $42.40) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

2. Summary

In section XV.B.4. of this proposed rule, we propose to: (1) Adopt the COVID19 Vaccination Coverage Among Health Care Personnel (HCP) measure, beginning with the CY 2022 reporting period; (2) adopt the Breast Screening Recall Rates measure, beginning with the CY 2022 reporting period; (3) adopt the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM, beginning as a voluntary measure with the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period; (4) require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP–31) beginning with the CY 2023 reporting period/CY 2025 payment determination; (5) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (OP–37 a–e), with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination; (6) remove the Fibrinolytic Therapy Received Within 30 Minutes measure (OP2), effective with the CY 2023 reporting period; (7) remove the Median Time to Transfer to Another Facility for Acute Coronary Intervention measure (OP–3), effective with the CY 2023 reporting period; (8) remove the option for hospitals to send medical records to the CMS Data Abstraction Center (CDAC) via paper and removable media and require electronic submission for validation; (9) reduce the number of days hospitals have to submit medical records to the CDAC from 45 days to 30 days for validation; (10) enhance the targeting criteria used for hospital selection for validation by adopting criteria currently used in inpatient data validation by adding the following criteria: (a) Having a lower bound confidence interval score of 75 percent or less; and (b) having not been selected in the previous 3 years; (11) expand our Extraordinary Circumstances Exception (ECE) policy to apply to electronic clinical quality measures (eCQMs), to further align with the Hospital IQR Program; (12) require use of technology updated consistent with 2015 Edition Cures Update criteria beginning with the CY 2023 reporting period/CY 2025 payment determination; and (13) provide a review and corrections period for eCQM data submitted to the Hospital OQR Program.

3. Estimated Burden of Hospital OQR Program Proposals for the CY 2024 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for the Proposed COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure

In section XV.B.4.a. of this proposed rule, we are proposing to adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period/CY 2024 payment determination. Hospitals would submit data through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based surveillance system maintained and provided free by the CDC. Currently, the CDC does not estimate burden for COVID–19

[438] *https://www.bls.gov/oes/current/oes292098.htm* (Accessed April 13, 2021). The hourly rate of $42.40 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

vaccination reporting under the CDC PRA (OMB control number 0920–1317, which expires on January 31, 2024) because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[439] As such, the proposed measure would not impose any additional information collection under the Paperwork Reduction Act for hospitals for the duration of the public health emergency (PHE). Although the burden associated with the COVID–19 Vaccination Coverage Among HCP measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666 (which expires on December 31, 2023) due to the NCVIA waiver, the cost and burden information is included in the Regulatory Impact Analysis section. Upon receiving comment, we will work with CDC to ensure that this burden is accounted for in an updated PRA under OMB control number 0920–1317.

b. Information Collection Burden Estimate for the Proposed Breast Screening Recall Rates Measure

In section XV.B.4.b. of this proposed rule, we are proposing to adopt the Breast Screening Recall Rates measure, beginning with the CY 2023 payment determination using a data collection period of July 1, 2020, to June 30, 2021; for subsequent years, we would use data collection periods from July 1 through June 30 for the 3 years prior to the applicable payment calendar year (for example, for the CY 2024 payment determination, we would use data from July 1, 2021, through June 30, 2022). Because the measure is calculated using claims data that are already reported to the Medicare program for payment purposes, we do not anticipate that adopting this measure will result in any increase in information collection burden.

c. Information Collection Burden Estimate for the Proposed ST-Segment Elevation Myocardial Infarction (STEMI) Measure

In section XV.B.4.c. of this proposed rule, we are proposing to adopt the STEMI eCQM, with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination. For the CY 2023 voluntary reporting period, hospitals would be able to voluntarily report the measure for one or more quarters during the year. In subsequent years, we have proposed to gradually increase the number of quarters of data hospitals would be required to report on the measure starting with one self-selected quarter for the CY 2024 reporting period/CY 2026 payment determination, two self-selected quarters for the CY 2025 reporting period/CY 2027 payment determination, three self-selected quarters for the CY 2026 reporting period/CY 2028 payment determination, and four quarters for the CY 2027 reporting period/CY 2029 payment determination and for subsequent years.

For the voluntary reporting period in CY 2023, we estimate 20 percent of hospitals would report at least one quarter of data for the measure with 100 percent of hospitals reporting the measure as required in subsequent years. Based on experience with reporting of eCQMs on the Hospital IQR program, we are aligning our estimate of the time required for a Medical Records and Health Information Technician professional to submit the data required for the measure to be 10 minutes per quarter for each hospital. For the CY 2023 voluntary reporting period, we estimate an annual burden for all participating hospitals of 110 hours (3,300 hospitals × 20 percent × .1667 hours × 1 quarter) at a cost of $4,664 (110 hours × $42.40). For the CY 2024 reporting period/CY 2026 payment determination, we estimate the annual burden for all hospitals to be 550 hours (3,300 hospitals × .1667 hours × 1 quarters) at a cost of $23,320 (550 hours × $42.40). For the CY 2025 reporting period/CY 2027 payment determination, we estimate the annual burden for all hospitals to be 1,100 hours (3,300 hospitals × .1667 hours × 2 quarters) at a cost of $46,640 (1,100 hours × $42.40). For the CY 2026 reporting period/CY 2028 payment determination, we estimate the annual burden for all hospitals to be 1,650 hours (3,300 hospitals × .1667 hours × 3 quarters) at a cost of $69,960 (1,650 hours × $42.40). For the CY 2027 reporting period/CY 2029 payment determination and subsequent years, we estimate the annual burden for all hospitals to be 2,200 hours (3,300 hospitals × .1667 hours × 4 quarters) at a cost of $93,280 (2,200 hours × $42.40).

The information collection requirement and the associated burden will be submitted as part of a revision of the information collection request currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

d. Information Collection Burden Estimate for the Proposal To Require the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure (OP–31)

In section XV.B.5.b. of this proposed rule, we are proposing to require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP–31), beginning with the CY 2023 reporting period/CY 2025 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPPS/ASC final rule (79 FR 66947 through 66948) and estimated that 20 percent of hospitals would elect to report it annually (79 FR 67014). We continue to estimate it will require hospitals 10 minutes once annually to report this measure using a CMS online tool. As a result of this proposal, we estimate a total annual burden estimate for all hospitals of 550 hours (3,300 hospitals × .1667 hours) at a cost of $23,320 (550 hours × $42.40). In addition to reporting the measure, we also require hospitals to perform chart abstraction and estimate that each hospital would spend 25 minutes (0.417 hours) per case to perform this activity. The currently approved burden estimate is based on an assumption of 384 cases requiring chart abstraction per measure. We are updating this assumption to 242 cases per measure based on data from the CY 2019 reporting period. Updating this assumption results in an annual burden of 101 hours (0.417 hours × 242 cases) at a cost of $4,282 (101 hours × $42.40/hour) per hospital and a total annual burden of 333,300 hours (3,300 hospitals × 101 hours) at a cost of $14,131,920 (333,300 hours × $42.40/hour) for all hospitals. In aggregate, we estimate a total annual burden of 333,850 hours (550 hours + 333,300 hours) at a cost of $14,155,240 ($23,320 + $14,131,920) for all hospitals. This is an increase of 267,080 hours and $11,324,192 per year from the currently approved estimate due to the additional 80 percent of hospitals that would be required to report this measure if our proposal is finalized.

The information collection requirement and the associated burden will be submitted as part of a revision of the information collection request currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

[439] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

e. Information Collection Burden Estimate for the Proposals To Require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures (OP–37a–e) and Add Administration Methods

The information collection requirements associated with the five OAS CAHPS survey-based measures (proposed OP–37a, OP–37b, OP–37c, OP–37d, and OP–37e) are currently approved under OMB control number 0938–1240 which expires December 31, 2021. In section XV.B.5.a. of this proposed rule, we are proposing to require data collection for five OAS CAHPS survey-based measures with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination and subsequent years: (1) OAS CAHPS—About Facilities and Staff (OP–37a); (2) OAS CAHPS—Communication About Procedure (OP–37b); (3) OAS CAHPS—Preparation for Discharge and Recovery (OP–37c); (4) OAS CAHPS—Overall Rating of Facility (OP–37d); and (5) OAS CAHPS—Recommendation of Facility (OP–37e). This proposal will neither require additional questions to be added to the survey nor any other changes which will affect the time required for respondents to complete the survey. Therefore, we are not making any changes to the currently approved burden estimate of 8 minutes per respondent.

In addition, in section XV.D.4.b. of this proposed rule, we are proposing to incorporate two additional administration methods for the OAS CAHPS Survey: (1) Mixed mode web with mail follow-up of non-respondents, and (2) mixed mode web with telephone follow-up of non-respondents. This proposal would allow a total of five methods of survey administration for reporting beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting for the CY 2024 reporting period/CY 2026 payment determination. We currently assume that completion of the OAS CAHPS survey requires approximately 8 minutes per respondent using one of the three current administration methods (mail-only, telephone-only, and mixed-mode (mail with telephone follow-up of non-respondents)). The two proposed administration methods would be utilized to increase the response rate of patients in order to achieve the same required number of 300 patients surveyed per practice, therefore we are not proposing any changes to the number of respondents. We also believe that both of the two proposed administration methods will require approximately the same time to conduct, therefore, we are not proposing any changes to the currently approved estimate.

f. Information Collection Burden Change for the Proposals To Remove the Fibrinolytic Therapy Received Within 30 Minutes (OP–2) and Median Time To Transfer to Another Facility for Acute Coronary Intervention (OP–3) Measures

In section XV.B.3.c. of this proposed rule, we are proposing to remove the Fibrinolytic Therapy Received Within 30 Minutes (OP–2) and Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP–3) measures effective with the CY 2023 reporting period. The currently approved burden estimate under OMB control number 0938–1109 (which expires on March 31, 2023) for all hospitals is 151,800 hours at a cost of $6,436,320 (151,800 hours × $42.40) for each measure per year. If the proposals to remove both of these measures are finalized, we estimate a total burden decrease of 303,600 hours (151,800 hours × 2 measures) at a cost of $12,872,640 (303,600 hours × $42.40). The information collection under OMB Control number 0938–1109 will be revised and submitted to OMB for approval.

g. Information Collection Burden Estimate for the Proposal To Remove the Option for Hospitals To Send Medical Records to the Validation Contractor via Paper and Removable Media and Require Electronic Submission

As noted in the CY 2015 OPPS/ASC final rule (79 FR 67015), we have been reimbursing hospitals directly for expenses associated with submission of medical records for data validation. Specifically, we reimburse hospitals at 12 cents per photocopied page; for hospitals providing medical records digitally via a rewritable disc, such as encrypted Compact Disc—Read Only Memory, Digital Video Discs, or flash drives, we reimburse hospitals at a rate of 40 cents per disc, along with $3.00 per record; and for hospitals providing medical records as electronic files submitted via secure file transmission, we reimburse hospitals at $3.00 per record. Because we directly reimburse, we do not anticipate any net change in information collection burden associated with our finalized proposal to require electronic file submissions of medical records via secure file transmission for hospitals selected for chart-abstracted measures validation. Hospitals would continue to be reimbursed at $3.00 per record for electronic files submitted via secure file transmission, if our proposal is finalized.

h. Information Collection Burden Estimate for the Proposal To Reduce the Number of Days Hospitals Have To Submit Medical Records to the CDAC From 45 Days to 30 Days

In section XV.D.9.b. of this proposed rule, we are proposing to reduce the number of days hospitals would have to submit medical records to the CDAC from 45 days to 30 days. We expect that our proposal will not yield a change in burden as it does not affect the amount of data required for hospitals to submit. We discuss administrative burdens regarding this proposal in section XXV.C.4.b. of this proposed rule. The existing information collection requirement and the associated burden are currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

i. Information Collection Burden Estimate for the Proposal To Add the Targeting Criteria Used for Hospital Selection by Adopting Criteria Currently Used in Inpatient Data Validation

In section XV.D.9.d.(2). of this proposed rule, we are proposing to add to the targeting criteria used for hospital selection for validation by adopting criteria currently used in inpatient data validation by adding the following criteria: (a) Having a lower bound confidence interval score of 75 percent or less; and (b) having not been selected in the previous 3 years. We expect that our proposal will not yield a change in burden as it does not affect the total number of hospitals selected for data validation nor the data submission requirements for the hospitals selected. The existing information collection requirement and the associated burden are currently approved under OMB control number 0938–1109, which expires on March 31, 2023.

j. Information Collection Burden Estimate for the Proposal To Expand Our Existing ECE Policy To Apply to Electronic Clinical Quality Measures (eCQMs)

In section XV.D.10.b. of this proposed rule, we are proposing to expand our existing ECE policy to apply to eCQMs, to further align with the Hospital IQR Program. The burden associated with submission of the ECE request form is included under OMB control number 0938–1022 which expires on December 31, 2022. As noted in 0938–1022, the total estimated burden for all hospitals

participating in the CMS Quality Reporting Program for completing forms including the ECE request form is 1,100 hours. In CY 2017, 166 ECE requests were submitted by hospitals for an exception from reporting requirements in the Hospital IQR Program. Based on the estimate of 15 minutes per record to submit the ECE Request Form, the total burden calculation for the submission of 166 ECE requests was 2,490 minutes (or 41.5 hours) across 3,300 IPPS hospitals. We are unable to forecast the number of additional ECE requests which may be submitted as a result of this proposal, however we continue to assume that each submission will continue to require approximately 15 minutes to complete. We believe the estimate of 1,100 hours across all IPPS and non-IPPS hospitals is conservative enough to account for any increase in burden that may be associated with this proposal.

k. Information Collection Burden Estimate for the Proposal To Require Use of 2015 Edition Cures Update Certified Technology

In section XV.D.6.c.(1). of this proposed rule, we are proposing hospitals use certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY 2023 reporting period/CY 2025 payment determination and subsequent years, which includes both the voluntary period and required submissions of eCQMs. We do not expect that this proposal, if finalized, would affect our information collection burden estimates currently approved under OMB control number 0938–1109 (which expires on March 31, 2023) because this policy does not require hospitals to submit additional data to CMS. With respect to any costs unrelated to data submission, we refer readers to section XXV.C.4.b. of this proposed rule.

l. Information Collection Burden Estimate for the Proposal To Provide a Review and Corrections Period for eCQM Data Submitted to the Hospital OQR Program

In section XV.D.8. of this proposed rule, we are proposing that hospitals would have a review and corrections period for eCQM data submitted to the Hospital OQR Program. Early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting is encouraged but not required; therefore, we are unable to estimate the number of hospitals that may elect to submit test data files. We account for the burden of submission of production data files in section XXIII.B.3.C. Similar to our previously finalized burden assumptions regarding a review and corrections period for chart-abstracted measures (79 FR 66964 and 67014) and web-based measures (85 FR 86184 and 86267) this proposal does not require hospitals to submit additional data, therefore we do not believe it will increase burden for these hospitals.

4. Summary of Information Collection Burden Estimates for the Hospital OQR Program

In summary, under OMB control number 0938–1109 which expires on March 31, 2023, we estimate that the policies promulgated in this proposed rule will result in a decrease of 73,344 hours annually for 3,300 OPPS hospitals across a 5-year period from the CY 2022 reporting period/CY 2024 payment determination through the CY 2027 reporting period/CY 2029 payment determination. The total cost decrease related to this information collection is approximately −$3,109,786 (−73,344 hours × $42.40/hour) (which also reflects use of an updated hourly wage rate as previously discussed). Tables 65, 66, 67, 68, and 69 summarize the total burden changes for each respective CY payment determination compared to our currently approved information collection burden estimates (the table for the CY 2029 payment determination reflects the cumulative burden changes). Note that for the proposed STEMI eCQM, the tables do not reflect the maximum burden for the CY 2025 payment determination, because we estimate only 20 percent of hospitals will voluntarily report the measure during the CY 2023 reporting period. While it is possible that more than 20 percent of hospitals may voluntarily report the measure during the CY 2023 reporting period, this percentage is consistent with our experience implementing eCQM measures with voluntary reporting periods under the Hospital IQR Program. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109.[440]

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[440] CY 2020 Final Rule Hospital OQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911–0938–015*.

TABLE 65: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2023 Reporting Period/CY 2025 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2025 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add STEMI Measure	10	4	660	1	0.67	440	N/A	+440
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -75,104							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-75,104) = **-$3,184,410**							

TABLE 66: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2024 Reporting Period/CY 2026 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2026 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add STEMI Measure	10	1	3,300	1	0.167	550	N/A	+550
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -74,994							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-74,994) = **-$3,179,746**							

TABLE 67: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2025 Reporting Period/CY 2027 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Payment Determinations							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add STEMI Measure	10	2	3,300	1	0.33	1,100	N/A	+1,100
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -74,444							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-74,444) = **-$3,156,426**							

TABLE 68: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2026 Reporting Period/CY 2028 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2028 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add STEMI Measure	10	3	3,300	1	0.50	1,650	N/A	+1,650
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -73,894							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-73,894) = **-$3,133,106**							

TABLE 69: Summary of Hospital OQR Program Information Collection Burden Change for the CY 2027 Reporting Period/CY 2029 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2029 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Add STEMI Measure	10	4	3,300	1	0.67	2,200	N/A	+2,200
Require OP-31 Measure	10	1	3,300	1	0.167	550	110	+440
Require Chart Abstraction for OP-31 measure	25	1	3,300	242	101	333,300	105,684	+227,616
Remove OP-2 Measure	0	0	0	0	0	0	151,800	-151,800
Remove OP-3 Measure	0	0	0	0	0	0	151,800	-151,800
	Total Change in Information Collection Burden Hours: -73,344							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (-73,344) = **-$3,109,786**							

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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, CY 2018, CY 2019, CY 2020, and CY 2021 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; 82 FR 59479 through 59481; 83 FR 59156 through 59157; 84 FR 61469; and 85 FR 86267, respectively) for detailed discussions of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program ICRs we have previously finalized. The ICRs associated with the ASCQR Program for the CY 2014 through CY 2023 payment determinations are currently approved under OMB control number 0938–1270, which expires on December 31, 2022.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52619 through 52620), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the BLS, to calculate our burden estimates for the ASCQR Program. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the ASCQR Program. The latest data from the BLS' May 2020 Occupational Employment and Wages data reflects a median hourly wage of $21.20 per hour for a Medical Records and Health Information Technician professional.[441] We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52619 through 52620). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($21.20 × 2 = $42.40) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

Based on an analysis of the CY 2020 payment determination data, we found that of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 3,494 were required to participate in the Program and did so.

[441] *https://www.bls.gov/oes/current/oes292098.htm* (Accessed April 13, 2021). The hourly rate of $42.40 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

In addition, 689 ASCs that were not required to participate, did so, for a total of 4,183 participating facilities. As noted in section XXV.C.5.a. of the Regulatory Impact Analysis, for the CY 2021 payment determination, all 6,811 ASCs that met eligibility requirements for the ASCQR Program received the annual payment update due to data submission requirements being excepted under the ASCQR Program's ECEs policy in consideration of the COVID–19 PHE; of these 3,957 would have been were required to participate sans the PHE exception. Therefore, we estimate that 3,957 plus 689 or 4,646 ASCs will submit data for the ASCQR Program for the CY 2022 payment determination unless otherwise noted.

2. Summary

In this proposed rule, we propose to: (1) Adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period/CY 2024 payment determination; (2) require four patient safety outcome measures beginning with the CY 2023 reporting period/CY 2025 payment determination: (a) Patient Burn (ASC–1); (b) Patient Fall (ASC–2); (c) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and (d) All-Cause Hospital Transfer/Admission (ASC–4); (3) require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11) measure beginning with the CY 2023 reporting period/CY 2025 payment determination; (4) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (ASC–15 a–e), with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination; and (5) add two additional data collection survey modes of OAS CAHPS measures collection to the existing three modes of collection and provide survey administration requirements.

3. Estimated Burden of ASCQR Program Proposals for the CY 2024 Payment Determination and Subsequent Years

a. Information Collection Burden Estimate for the Proposed COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure

In section XVI.B.3.a. of the preamble of this proposed rule, we are proposing to adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period/CY 2024 payment determination. ASCs would submit data through the CDC/NHSN. The NHSN is a secure, internet-based surveillance system maintained and provided free by the CDC. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA (OMB control number 0920–1317, which expires on January 31, 2024) because the agency has been granted a waiver under section 321 of the NCVIA.[442] As such, the burden associated with the COVID–19 Vaccination Coverage Among HCP measure has not been accounted for under the CDC PRA 0920–1317 or 0920–0666 (which expires on December 31, 2023) due to the NCVIA waiver, however the cost and burden information is included in the Regulatory Impact Analysis section. Upon receiving comment, we will work with CDC to ensure that the burden is accounted for in an updated PRA under OMB control number 0920–1317.

b. Information Collection Burden Estimate for the Proposal To Require Four Patient Safety Outcome Measures: Patient Burn (ASC–1); Patient Fall (ASC–2); Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and All-Cause Hospital Transfer/Admission (ASC–4)

In section XVI.B.4.a. of this proposed rule, we are proposing to resume and require four patient safety outcome measures beginning with the CY 2023 reporting period/CY 2025 payment determination: (1) Patient Burn (ASC–1); (2) Patient Fall (ASC–2); (3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and (4) All-Cause Hospital Transfer/Admission (ASC–4). Measure data for these measures would be submitted via the CMS Hospital Quality Reporting (HQR) system secure portal (also known as the CMS QualityNet Secure Portal). Consistent with prior years (78 FR 75171 through 75172), we estimate that each participating hospital will spend 10 minutes per measure per year to collect and submit the data via a CMS web-based tool (OMB control number 0938–1270, which expires on December 31, 2022). As a result of this proposal, we estimate a total annual burden estimate for all ASCs of 3,098 hours (0.1667 hours/measure × 4 measures × 4,646 ASCs) at a cost of $131,355 (3,098 hours × $42.40). The information collection under OMB Control number 0938–1270 will be revised and submitted to OMB for approval.

c. Information Collection Burden Estimate for the Proposal To Require the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (ASC–11) Measure

In section XVI.B.4.b. of this proposed rule, we are proposing to require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11) measure beginning with the CY 2023 reporting period/CY 2025 payment determination. We previously finalized voluntary reporting of this measure in the CY 2015 OPPS/ASC final rule (79 FR 66985) and estimated that 20 percent of ASCs would elect to report it annually (79 FR 67016). We continue to estimate it will require ASCs 10 minutes once annually to report this measure. As a result of this proposal, we estimate a total annual burden estimate for all ASCs to report the measure of 774 hours (4,646 ASCs × 0.1667 hours) at a cost of $32,818 (774 hours × $42.40). In addition to reporting the measure, we also require ASCs to perform chart abstraction for a minimum required yearly sample size of 63 cases. We estimate that each ASC would spend 15 minutes per case to perform this activity. As a result of this proposal, we estimate an annual burden of 16 hours (0.25 hours × 63 measures) at a cost of $678 (16 hours × $42.40) per ASC and a total annual burden of 74,336 hours (4,646 ASCs × 16 hours) at a cost of $3,151,846 (74,336 hours × $42.40). In aggregate, we estimate a total annual burden of 75,110 hours (774 + 74,336) at a cost of $3,184,664 (75,110 hours × $42.40) for all ASCs. Taking into account the increase in the number of ASCs submitting data, this is an increase of 60,088 hours (75,110 hours × 80 percent) and $2,547,731 ($3,184,664 × 80 percent) per year from the currently approved estimate (OMB control number 0938–1270, which expires on December 31, 2022) due to the additional 80 percent of ASCs that would be reporting this measure if our proposal is finalized. The information collection under OMB Control number 0938–1270 will be revised and submitted to OMB for approval.

[442] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

d. Information Collection Burden Estimate for the Proposals To Require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures (ASC–15 a–e) and Incorporate Additional Administration Methods

The information collection requirements associated with the five OAS CAHPS Survey-based measures (proposed ASC–15a, ASC–15b, ASC–15c, ASC–15d, and ASC–15e) are currently approved under OMB control number 0938–1240 which expires December 31, 2021.

In section XVI.B.4.c. of this proposed rule, we are proposing to require five OAS CAHPS Survey-based measures with voluntary reporting beginning with the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination and subsequent years: (1) ASC–15a: OAS CAHPS—About Facilities and Staff; (2) ASC–15b: OAS CAHPS—Communication About Procedure; (3) ASC–15c: OAS CAHPS—Preparation for Discharge and Recovery; (4) ASC–15d: OAS CAHPS—Overall Rating of Facility; and (5) ASC–15e: OAS CAHPS—Recommendation of Facility. This proposal will neither require additional questions to be added to the survey nor any other changes which will affect the time required for respondents to complete the survey. Therefore, we are not making any changes to the currently approved burden estimate of 8 minutes per respondent.

In addition, in section XVI.D.1.d.(2). of this proposed rule, we are proposing to incorporate two additional administration methods for the OAS CAHPS Survey: (1) Mixed mode web with mail follow-up of non-respondents, and (2) mixed mode web with telephone follow-up of non-respondents. This proposal would allow a total of five methods of survey administration for reporting beginning with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting for the CY 2024 reporting period/CY 2026 payment determination. We currently assume that completion of the OAS CAHPS survey requires approximately 8 minutes per respondent using one of the three current administration methods (mail-only, telephone-only, and mixed-mode (mail with telephone follow-up of nonrespondents)). We believe that both of the two proposed administration methods will require approximately the same time to conduct, therefore, we are not proposing any changes to the currently approved estimate. In addition, the two proposed administration methods would be utilized to increase the response rate of patients in order to achieve the same required number of 300 patients surveyed per practice, therefore we are not proposing any changes to the number of respondents.

e. Summary of Information Collection Burden Estimates for the ASCQR Program

In summary, under OMB control number 0938–1270 which expires on December 31, 2022, we estimate that the policies promulgated in this proposed rule will result in an increase of 67,085 hours annually for 4,646 ASCs across a 4-year period from the CY 2023 reporting period/CY 2025 payment determination through the CY 2026 reporting period/CY 2028 payment determination. The total cost increase related to this information collection is approximately $2,844,404 (67,085 hours × $42.40). Table 70 summarizes the total burden changes for each respective CY payment determination compared to our currently approved information collection burden estimates. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270.[443]

[443] CY 2021 Final Rule ASCQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/DownloadDocument?objectID=108544300.*

TABLE 70: Summary of ASCQR Program Information Collection Burden Change for the CY 2023 Reporting Period/CY 2025 Payment Determination through CY 2026 Reporting Period/CY 2028 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2025 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Require ASC 1-4 measures	10	1	4,646	4	0.67	3,098	N/A	+3,098
Require ASC-11 Measure	10	1	4,646	1	.1667	774	116.7	+657
Require Chart Abstraction for ASC-11 Measure	15	1	4,646	63	16	74,336	11,006	+63,330
	Total Change in Information Collection Burden Hours: +67,085							
	Total Cost Estimate: Updated Hourly Wage ($42.40) x Change in Burden Hours (+67,085) = **+$2,844,404**							

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by September 17, 2021.

XXIV. 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 preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XXV. Economic Analyses

A. Statement of Need

This proposed rule 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 2022. 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 propose to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2019, through and including December 31, 2019, and processed through June 30, 2020, and prior cost report information, consistent with our proposal to use data prior to the start of the PHE.

This proposed rule also is necessary to make updates to the ASC payment rates for CY 2022, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2022. 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.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI–U for CY 2019 through 2023. We believe that this policy will help 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 of Provisions of This Proposed Rule

We have examined the impacts of this proposed rule, 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 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). This section of this proposed rule contains the impact and other economic analyses for the provisions we propose for CY 2022.

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 proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866. Accordingly, this proposed rule 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 proposed rule. We are soliciting public comments on the regulatory impact analysis in the proposed rule, and we address any public comments we received in this proposed rule, as appropriate.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2022, compared to CY 2021, due only to the changes to the OPPS in this proposed rule, would be approximately $1.35 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2022, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2022 would be approximately $82.7 billion, which is approximately $10.8 billion higher than estimated OPPS expenditures in CY 2021. Because the provisions of the OPPS are part of a proposed 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 71 of this proposed rule displays the distributional impact of the CY 2022 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our proposed CY 2022 policy, drugs and biologicals that are acquired under the 340B Program are proposed 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 proposed update to the conversion factor and other budget neutrality adjustments would increase total OPPS payments by 2.3 percent in CY 2022. The proposed changes to the APC relative payment weights, the changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, the proposed continuation of payment policy for separately payable drugs acquired under the 340B program, and the proposed payment adjustment for cancer hospitals would not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2021 and CY 2022, considering all proposed budget-neutral payment adjustments, changes in estimated total outlier payments, pass-through payments and the proposed adjustment to provide separate payment for a device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022, and the application of the frontier State wage adjustment, 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, would increase total estimated OPPS payments by 1.8 percent.

We estimate the total decrease (from changes to the ASC provisions in this proposed rule 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 2022 compared to CY 2021, to be approximately $20 million. Because the provisions for the ASC payment system are part of a proposed 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 proposed rule. Tables 72 and 73 of this proposed rule display the redistributive impact of the CY 2022 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 Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2022 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2022 with the other supporting documentation for this proposed rule. 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–1753–P'' 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 proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 71. 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 proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting or 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 Proposal To Update the 340B Program Payment Policy

In section V.B. of this proposed rule with comment period, we discuss our proposal to adjust the payment amount for nonpass-through, separately payable drugs acquired by certain 340B participating hospitals through the 340B Program. We propose that rural SCHs, children's hospitals, and PPS-exempt cancer hospitals continue to be excepted from this payment policy in CY 2022. Specifically, in this proposed rule for CY 2022, for hospitals paid under the OPPS (other than those that are excepted for CY 2022), we propose to pay for separately payable drugs and

biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent. Because we are proposing to continue current Medicare payment policy for CY 2022, there is no change to the proposed budget neutrality adjustment as a result of the 340B drug payment policy.

c. Estimated Effects of OPPS Changes on Hospitals

Table 71 shows the estimated impact of this proposed rule 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 71, 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 2022, we propose to continue to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs) and to pay 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 proposed rule.

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 proposed IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2022 is 2.5 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 2.5 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.2 percentage point for CY 2022 (which is also the productivity adjustment for FY 2022 in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25436)), resulting in the CY 2022 OPD fee schedule increase factor of 2.3 percent. We are proposing to use the OPD fee schedule increase factor of 2.3 percent in the calculation of the CY 2022 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 estimates in Table 71 of this proposed rule.

To illustrate the impact of the CY 2022 changes, our analysis begins with a baseline simulation model that uses the CY 2021 relative payment weights, the FY 2021 final IPPS wage indexes that include reclassifications, and the final CY 2021 conversion factor. Table 71 shows the estimated redistribution of the increase or decrease in payments for CY 2022 over CY 2021 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2021 and CY 2022 (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 2.3 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for CY 2022 relative to all payments for CY 2021, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate and adjustment to provide separate payment for a device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022 (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are proposing to maintain the current adjustment percentage for CY 2022. 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 2022 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 proposed rule will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2021 and CY 2022 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2022 will increase Medicare OPPS payments by an estimated 1.8 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 1.8 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 71 shows the total number of facilities (3,662), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2019 hospital outpatient and CMHC claims data to model CY 2021 and CY 2022 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 2021 or CY 2022 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 proposed rule. 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 (3,555), 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 39 CMHCs at the bottom of the impact table (Table 71) 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 a decrease of 0.1 percent to an increase of 0.2, depending on the number of beds. Rural hospitals will experience an increase of 0.1 overall. Major teaching hospitals will see 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 proposed FY 2022 IPPS post-reclassification wage indexes; the proposed rural adjustment, and the proposed 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 2021 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 proposed updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the CY 2022 proposed changes in wage index policy discussed in section II.C. of this CY 2022 OPPS/ASC proposed rule. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we propose to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2022, as described in section II.E. of this proposed rule. We also did not model a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2022 is 0.89, the same as the ratio that was reported for the CY 2021 OPPS/ASC final rule with comment period (85 FR 85914). 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 0.90, not the 0.89 target payment-to-cost ratio we propose to apply in section II.F. of this proposed rule.

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 2022 scaled weights and a CY 2021 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2021 and CY 2022.

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 2.3 percent. Overall, these changes will increase payments to urban hospitals by 2.3 percent and to rural hospitals by 2.3 percent. The increase for classes of rural hospitals will vary with sole community hospitals receiving a 2.2 percent increase and other rural hospitals receiving an increase of 2.5 percent.

Column 5: All Proposed Changes for CY 2022

Column 5 depicts the full impact of the proposed CY 2022 policies on each hospital group by including the effect of all changes for CY 2022 and comparing them to all estimated payments in CY 2021. Column 5 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this proposed rule; 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 XIV. of this proposed rule); and the difference in total OPPS payments dedicated to transitional pass-through payments and the proposed adjustment to provide separate payment for the device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2021 update (and assumed, for modeling purposes, to be the same number for CY 2022), we included 17 hospitals in our model because they had both CY 2019 claims data and recent cost report data. We estimate that the cumulative effect of all proposed changes for CY 2022 will increase payments to all facilities by 1.8 percent for CY 2022. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2021 and the proposed relative payment weights for CY 2022. We used the final conversion factor for CY 2021 of $82.797 and the proposed CY 2022 conversion factor of $84.457 discussed in section II.B. of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the 2-year charge inflation factor used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039) of 13.2 percent (1.13218) to increase individual costs on the CY 2019 claims, and we used the overall CCR in the April 2020 Outpatient Provider-Specific File (OPSF) with a 1-year CCR adjustment factor of 0.974495 (85 FR 59040) to estimate outlier payments for CY 2021. Using the CY 2019 claims and a 13.2 percent charge inflation factor, we currently estimate that outlier payments for CY 2021, using a multiple threshold of 1.75 and a fixed-dollar threshold of $5,300, will be approximately 1.06 percent of total payments. The estimated current outlier payments of 1.06 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 20.4 percent (1.20469) and the CCRs in the April 2020 OPSF, with an adjustment of 0.974495 multiplied by 0.974495 (86 FR 25718), to reflect relative changes in cost and charge inflation between CY 2019 and CY 2022, to model the proposed CY 2022 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $6,100. The charge inflation and CCR inflation factors are discussed in detail in the FY 2021 IPPS/LTCH PPS proposed rule (84 FR 42629).

Overall, we estimate that facilities will experience an increase of 1.8 percent under this proposed rule in CY 2022 relative to total spending in CY 2021. This projected increase (shown in Column 5) of Table 71 reflects the 2.3 percent OPD fee schedule increase factor, minus 0.40 percent for the change in the pass-through payment estimate between CY 2021 and CY 2022 and the proposed adjustment to provide separate payment for the device category, drugs, and biologicals with pass-through status expiring between December 31, 2021, and September 30, 2022, minus the difference in estimated outlier payments between CY 2021 (1.06 percent) and CY 2022 (1.0 percent). We estimate that the combined effect of all proposed changes for CY 2022 will increase payments to urban hospitals by 1.8 percent. Overall, we estimate that rural hospitals will experience a 1.8 percent increase as a result of the

combined effects of all the proposed changes for CY 2022.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.7 percent for major teaching hospitals and an increase of 2.0 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 1.8 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 1.8 percent, proprietary hospitals will experience an increase of 2.0 percent, and governmental hospitals will experience an increase of 2.4 percent.

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TABLE 71: Estimated Impact of the Proposed CY 2022 Changes for the Hospital Outpatient Prospective Payment System

		(1)	(2)	(3)	(4)	(5)
		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**	**All Changes**
ALL PROVIDERS *		3,662	0.0	0.0	2.3	1.8
ALL HOSPITALS		3,555	0.0	0.0	2.3	1.8
	(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS		2,803	0.0	0.0	2.3	1.8
	LARGE URBAN	1,448	0.0	0.1	2.4	1.9
	(GT 1 MILL.)					
	OTHER URBAN	1,355	0.0	-0.1	2.2	1.8
	(LE 1 MILL.)					

		(1)	(2)	(3)	(4)	(5)
		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**	**All Changes**
RURAL HOSPITALS		752	0.1	0.0	2.3	1.8
	SOLE COMMUNITY	369	0.0	-0.1	2.2	1.7
	OTHER RURAL	383	0.1	0.1	2.5	2.0
BEDS (URBAN)						
	0 - 99 BEDS	958	0.2	0.0	2.5	2.0
	100-199 BEDS	786	0.1	-0.1	2.3	1.8
	200-299 BEDS	447	0.1	0.0	2.4	1.9
	300-499 BEDS	386	0.0	0.0	2.3	1.9
	500 + BEDS	226	-0.1	0.0	2.2	1.7
BEDS (RURAL)						
	0 - 49 BEDS	330	0.1	-0.3	2.2	1.7
	50- 100 BEDS	256	0.1	-0.1	2.3	1.8
	101- 149 BEDS	90	0.0	-0.2	2.1	1.7
	150- 199 BEDS	38	0.0	0.1	2.4	1.9
	200 + BEDS	38	0.0	0.4	2.6	2.1
REGION (URBAN)						
	NEW ENGLAND	132	0.0	-0.3	2.0	1.5
	MIDDLE ATLANTIC	326	0.0	-0.4	1.9	1.4
	SOUTH ATLANTIC	455	0.0	0.2	2.6	2.1
	EAST NORTH CENT.	440	0.0	0.0	2.3	1.8
	EAST SOUTH CENT.	163	0.0	0.0	2.3	1.8
	WEST NORTH CENT.	186	0.0	0.3	2.6	2.2
	WEST SOUTH CENT.	474	0.1	-0.2	2.2	1.7
	MOUNTAIN	213	0.0	-0.1	2.2	1.6
	PACIFIC	366	0.1	0.3	2.7	2.2
	PUERTO RICO	48	0.3	-0.4	2.3	1.8
REGION (RURAL)						

		(1)	(2)	(3)	(4)	(5)
		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**	**All Changes**
	NEW ENGLAND	20	-0.1	-0.3	1.9	1.4
	MIDDLE ATLANTIC	50	0.1	0.1	2.4	1.9
	SOUTH ATLANTIC	113	0.1	0.6	3.0	2.5
	EAST NORTH CENT.	120	0.1	-0.1	2.3	1.8
	EAST SOUTH CENT.	146	0.1	-0.1	2.3	1.8
	WEST NORTH CENT.	91	0.0	-0.4	1.9	1.5
	WEST SOUTH CENT.	141	0.3	-0.1	2.5	2.0
	MOUNTAIN	48	-0.1	0.4	2.6	1.5
	PACIFIC	23	-0.1	-0.1	2.1	1.6
TEACHING STATUS						
	NON-TEACHING	2,388	0.1	0.0	2.5	2.0
	MINOR	792	0.0	-0.1	2.3	1.8
	MAJOR	375	-0.1	0.0	2.2	1.7
DSH PATIENT PERCENT						
	0	14	0.0	-0.4	1.9	1.4
	GT 0 - 0.10	270	0.2	-0.1	2.3	1.9
	0.10 - 0.16	235	0.1	-0.2	2.2	1.7
	0.16 - 0.23	577	0.2	0.0	2.5	2.0
	0.23 - 0.35	1,100	0.0	0.0	2.3	1.8
	GE 0.35	901	0.0	0.1	2.4	1.8
	DSH NOT AVAILABLE **	458	0.3	0.1	2.7	2.2
URBAN TEACHING/DSH						
	TEACHING & DSH	1,048	0.0	0.0	2.2	1.8
	NO TEACHING/DSH	1,303	0.1	0.1	2.5	2.0
	NO TEACHING/NO DSH	14	0.0	-0.4	1.9	1.4
	DSH NOT AVAILABLE2	438	0.3	0.1	2.7	2.2

		(1)	(2)	(3)	(4)	(5)
		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**	**All Changes**
TYPE OF OWNERSHIP						
	VOLUNTARY	1,975	0.0	0.0	2.3	1.8
	PROPRIETARY	1,131	0.3	-0.1	2.5	2.0
	GOVERNMENT	449	0.0	0.1	2.4	2.4
CMHCs		39	0.6	-0.8	2.1	1.6
Column (1) shows total hospitals and/or CMHCs.						
Column (2) includes all proposed CY 2022 OPPS policies and compares those to the CY 2021 OPPS.						
Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2022 hospital inpatient wage index. The proposed 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 1.0000 because the proposed CY 2022 target payment-to-cost ratio is the same as the CY 2021 PCR target (0.89).						
Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.3 percent OPD fee schedule update factor (2.5 percent reduced by 0.2 percentage point for the productivity adjustment).						
Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, the proposed adjustment to provide separate payment for the device category, drugs, and biologicals with pass-through status expiring between December 31, 2021 and September 30, 2022, and adding estimated outlier payments.						
These 3,662 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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d. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 71 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2021, 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 2019 claims used for ratesetting in the proposed rule. 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 1.6 percent increase in payments from CY 2021 (shown in Column 5). We note that this includes the trimming methodology as well as the proposed CY 2022 geometric mean costs used for developing the PHP payment rates described in section VIII.B. of this final rule with comment period.

Column 3 shows that the estimated impact of adopting the proposed FY 2021 wage index values will result in a decrease of 0.8 percent to CMHCs. Column 4 shows that combining this proposed OPD fee schedule increase factor, along with proposed changes in APC policy for CY 2022 and the proposed FY 2021 wage index updates, will result in an estimated increase of 2.1 percent. Column 5 shows that adding the proposed changes in outlier and pass-through payments will result in a total 1.6 percent increase in payment for CMHCs. This reflects all proposed changes for CMHCs for CY 2022.

e. 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 would 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 of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we

refer readers to section II.I. of this CY 2022 OPPS/ASC proposed rule. 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 would be 18.1 percent for all services paid under the OPPS in CY 2022. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2022 comprehensive APC payment policy discussed in section II.A.2.b. of this final rule.

f. 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 XIII of the final rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the proposed changes in the proposed rule.

g. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $1.35 billion in program payments for OPPS services furnished in CY 2022. 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 proposed changes in the proposed rule would increase these Medicaid beneficiary payments by approximately $95 million in CY 2022. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately thirty percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 30 percent 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 $95 million Medicaid increase, approximately $55 million will be from the Federal Government and $40 million would be from state governments.

h. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout the final rule.

- Alternatives Considered for the Claims Data used in OPPS and ASC Ratesetting due to the PHE.

We refer readers to section X.E. of this proposed rule with comment period for a discussion of our proposed policy of generally using claims, cost report and other data prior to the PHE. We note that in that section we discuss the alternative proposal we considered regarding applying the standard ratesetting process, in particular the selection of data used, which would include claims and cost report data including the timeframe of the PHE. We note that there are potential issues related to that data including the effect of the PHE on the OPPS relative payment weights and the service mix applied in the budget neutrality process, and therefore our primary proposal is to use CY 2019 claims and cost report data generally in CY 2022 OPPS ratesetting. However, we are making the supporting data files typically included as part of the rulemaking process, available online at the CMS website to allow stakeholders the opportunity to provide meaningful comment.

We note that these policy considerations also have ASC implications since the relative weights for certain surgical procedures performed in the ASC setting are developed based on the OPPS relative weights and claims data.

2. Estimated Effects of CY 2022 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this proposed rule, we are setting the CY 2022 ASC relative payment weights by scaling the proposed CY 2022 OPPS relative payment weights by the proposed ASC scalar of 0.8591. The estimated effects of the proposed updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 72 and 73.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which, in CY 2019, we adopted a policy to be the hospital market basket for CY 2019 through CY 2023) after application of any quality reporting reduction be reduced by a productivity adjustment. Section 1886(b)(3)(B)(xi)(II) of the 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, we propose that the CY 2022 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which we propose would be the hospital market basket for CY 2022. We calculated the CY 2022 ASC conversion factor by adjusting the CY 2021 ASC conversion factor by 0.9993 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2021 and CY 2022 and by applying the CY 2022 productivity-adjusted hospital market basket update factor of 2.3 percent (which is equal to the projected hospital market basket update of 2.5 percent reduced by a productivity adjustment of 0.2 percentage point). The proposed CY 2022 ASC conversion factor is $50.043 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2022 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2019 and CY 2022 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2022 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 proposed update to the CY 2022 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

proposed CY 2022 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2019 claims data. Table 72 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2021 payments to estimated proposed CY 2022 payments, and Table 73 shows a comparison of estimated CY 2021 payments to estimated proposed CY 2022 payments for procedures that we estimate will receive the most Medicare payment in CY 2021.

In Table 72, 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 72.

- 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 2021 ASC Payments were calculated using CY 2019 ASC utilization data (the most recent full year of ASC utilization) and CY 2021 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2021 ASC payments.
- Column 3—Estimated CY 2022 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 is attributable to proposed updates to ASC payment rates for CY 2022 compared to CY 2021.

As shown in Table 72, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2022 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, 4-percent increase in aggregate payment amounts for digestive system procedures, a 4-percent increase in aggregate payment amounts for musculoskeletal system procedures, and a 4-percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and proposed changes in policy. In general, spending in each of these categories of services is increasing due to the 2.3 percent proposed 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 2.3-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 4-percent increase in proposed aggregate gastrointestinal procedure payments. The increases in payment weights for gastrointestinal procedure payments is further increased by the proposed 2.3 percent ASC rate update for these procedures. For estimated changes for selected procedures, we refer readers to Table 73 provided later in this section.

TABLE 72: ESTIMATED IMPACT OF THE PROPOSED CY 2022 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2022 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2021 ASC Payments (in Millions) (2)	Estimated CY 2022 Percent Change (3)
Total	$5,681	2
Musculoskeletal	$727	4
Gastrointestinal	$948	4
Genitourinary	$213	4
Skin	$157	3
Eye	$1,918	-1
Nervous System	$1,211	3

Table 73 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2022. The table displays 30 of the procedures receiving the greatest estimated CY 2021 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2021 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2021 ASC Payments were calculated using CY 2019 ASC utilization (the most recent full year of ASC utilization) and the CY 2021 ASC payment rates. The estimated CY 2021 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2022 Percent Change reflects the percent differences between the estimated ASC

payment for CY 2021 and the estimated payment for CY 2022 based on the proposed update.

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TABLE 73: ESTIMATED IMPACT OF THE FINAL CY 2022 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2021 ASC Payment (in millions) (3)	Estimated CY 2022 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,293	1
63685	Insrt/redo spine n generator	$293	2
45380	Colonoscopy and biopsy	$251	3
45385	Colonoscopy w/lesion removal	$187	3
63650	Implant neuroelectrodes	$187	3
43239	Egd biopsy single/multiple	$186	3
0191T	Insert ant segment drain int	$128	0
64483	Inj foramen epidural l/s	$122	3
66982	Xcapsl ctrc rmvl cplx wo ecp	$96	1
64635	Destroy lumb/sac facet jnt	$86	4
64493	Inj paravert f jnt l/s 1 lev	$79	3
36902	Intro cath dialysis circuit	$78	3
29827	Sho arthrs srg rt8tr cuf rpr	$76	4
66821	After cataract laser surgery	$67	3
64590	Insrt/redo pn/gastr stimul	$63	3
C9740	Cysto impl 4 or more	$58	3
22869	Insj stablj dev w/o dcmprn	$58	3
62323	Njx interlaminar lmbr/sac	$55	3
G0105	Colorectal scrn; hi risk ind	$53	3
15823	Revision of upper eyelid	$41	3
45378	Diagnostic colonoscopy	$39	3
G0121	Colon ca scrn not hi rsk ind	$39	3
64721	Carpal tunnel surgery	$37	4
63655	Implant neuroelectrodes	$32	3
65820	Relieve inner eye pressure	$30	3
62362	Implant spine infusion pump	$28	3
67042	Vit for macular hole	$28	3
29881	Knee arthroscopy/surgery	$28	4
64490	Inj paravert f jnt c/t 1 lev	$28	3
64561	Implant neuroelectrodes	$28	3

c. Estimated Effects of Proposed ASC Payment System Policies on Beneficiaries

We estimate that the proposed CY 2022 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 propose to designate as office-based for CY 2022. For example, using 2019 utilization data and proposed CY 2022 OPPS and ASC payment rates, we estimate that if 10 percent of colpopexy procedures migrate from the hospital outpatient setting to the ASC setting, Medicare payments will be reduced by approximately $7 million in CY 2022 and total beneficiary copayments will decline by approximately $1.4 million in CY 2022. 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 hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the

hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the 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 ratesetting methodology or at the nonfacility practice expense based amount payable under the PFS. For those additional procedures that we propose to designate as office-based in CY 2022, 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).

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/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html*), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this proposed rule. The first accounting statement, Table 74, illustrates the classification of expenditures for the CY 2022 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2022 OPD fee schedule increase. The second accounting statement, Table 75, illustrates the classification of expenditures associated with the 2.3 percent CY 2022 update to the ASC payment system, based on the provisions of the final rule with comment period and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers.

TABLE 74: ACCOUNTING STATEMENT: CY 2022 Estimated Hospital OPPS Transfers from CY 2021 to CY 2022 Associated with the Proposed CY 2022 Hospital Outpatient OPD Fee Schedule Increase

Category	Transfers
Annualized Monetized Transfers	$1,350 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	$1,350 million

TABLE 75: ACCOUNTING STATEMENT: Classification of Estimated Transfers from CY 2021 to CY 2022 as a Result of the Proposed CY 2022 Update to the ASC Payment System

Category	Transfers
Annualized Monetized Transfers	$90 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$90 million

TABLE 76: Estimated Costs in CY 2022

CATEGORY	Costs
Burden	$4.54 million*
Regulatory Familiarization	$1.195 million**

*The annual estimate includes the impact of OQR and ASCQR program, vaccination coverage data collection across hospitals and ASCs, burden estimate for RO model, and burden reduction for State forensic hospitals.
** Regulatory familiarization costs occur upfront only.

TABLE 77: Accounting Statement Estimated Impacts for the Radiation Oncology Model

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	-$27 million	2020	7%	2022 – 2026
	-$29 million	2020	3%	2022 – 2026
From Whom to Whom	From the Federal Government to healthcare providers			

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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 Outpatient Quality Reporting (OQR) Program for the CY 2018, CY 2019, and CY 2021 payment determinations. Of the 3,163 hospitals that met eligibility requirements for the CY 2021 payment determination, we determined that 77 hospitals did not meet the requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor.

b. Impact of Proposals in This CY 2022 OPPS/ASC Proposed Rule

We anticipate that some of the CY 2022 Hospital OQR Program proposed policies, if finalized, will impact the number of facilities that will receive payment reductions. In this proposed rule with comment period, we are proposing to: (1) Adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period; (2) adopt the Breast Screening Recall Rates measure, beginning with the CY 2022 reporting period; (3) adopt the STEMI eCQM, beginning as a voluntary measure with the CY 2023 reporting period, and then as a mandatory measure beginning with the CY 2024 reporting period; (4) require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery measure (OP–31), beginning with the CY 2023 reporting period/CY 2025 payment determination; (5) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (OP–37a–e), with voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination; (6) remove the Fibrinolytic Therapy Received Within 30 Minutes measure (OP–2), effective with the CY 2023 reporting period; (7) remove the Median Time to Transfer to Another Facility for Acute Coronary Intervention measure (OP–3), effective with the CY 2023 reporting period; (8) remove the option for hospitals to send medical records to the validation contractor via paper and removable media and require electronic submission; (9) reduce the number of days hospitals have to submit medical records to the CDAC from 45 days to 30 days; (10) enhance the targeting criteria used for hospital selection by adopting criteria currently used in inpatient data validation by adding the following criteria: (a) Having a lower bound confidence interval score of 75 percent or less; and (b) having not been selected in the previous 3 years; (11) extend our existing ECE policy to apply to eCQMs, to further align with the Hospital Inpatient Quality Reporting (IQR) Program; and (12) require use of technology updated consistent with 2015 Edition Cures Update criteria beginning with the CY 2023 reporting period.

As shown in Table 69 in section XXIII.B.4. (Collection of Information), we estimate a total information collection burden decrease for 3,300 OPPS hospitals of −73,344 hours at a cost of −$3,109,786 annually associated with our proposed policies and updated burden estimates across a 5 year period from the CY 2022 reporting period/CY 2024 payment determination through the CY 2027 reporting period/CY 2029 payment determination, compared to our currently approved information collection burden estimates. We refer readers to section XXII.B. of the preamble of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital OQR Program. As discussed later in this section of the preamble, we detail proposed policies that would have additional economic impact. The proposals not discussed in this section are believed to have no further economic impact beyond information collection burden.

In section XV.B.4.a. of the preamble of this proposed rule, we are proposing to adopt a COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2022 reporting period/CY 2024 payment determination. Hospitals would submit data through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[444] Although the burden associated with the COVID–19 Vaccination Coverage Among HCP measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666, the cost and burden information is included here. We estimate that it would take each hospital on average approximately 1 hour per month to collect data for the COVID–19 Vaccination Coverage Among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe an Administrative Assistant[445] would spend between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. Beginning with the CY 2022 reporting period/FY 2024 payment determination, hospitals

[444] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[445] *https://www.bls.gov/oes/current/oes436013.htm.* Accessed on April 13, 2021. The adjusted hourly wage rate of $35.92/hr includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

would incur an additional annual burden between 9 hours (0.75 hours/month × 12 months) and 15 hours (1.25 hours/month × 12 months) per hospital and between 29,700 hours (9 hours/hospital × 3,300 hospitals) and 49,500 hours (15 hours/hospital × 3,300 hospitals) for all hospitals. Each hospital would incur an estimated cost of between $323.28 (9 hours × $35.92/hr) and $538.80 annually (15 hours × $35.92/hr). The estimated cost across all 3,300 hospitals would be between $1,066,824 ($323.28/hospital × 3,300 hospitals) and $1,778,040 ($538.80/hospital × 3,300 hospitals) annually thereafter. We recognize that many healthcare facilities are also reporting other COVID–19 data to HHS. We believe the benefits of reporting data on the COVID–19 Vaccination Coverage Among HCP measure to monitor, track, and provide transparency for the public on this important tool to combat COVID–19 outweigh the costs of reporting. We welcome comments on the estimated time to collect data and enter it into the NHSN as well as any additional costs associated with this measure.

In section XV.B.4.c. of this proposed rule, we are proposing to adopt the STEMI eCQM. Similar to the FY 2019 IPPS/LTCH PPS final rule, we believe that costs associated with adoption of eCQMs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining Program requirements, such as maintaining measure specifications in hospitals EHR systems for all of the eCQMs available for use in the Hospital OQR Program (83 FR 41771).

As described in section XV.D.6. of this proposed rule, we are proposing certification requirements requiring the use of the 2015 Edition Cures Update for eCQMs beginning with the CY 2025 payment determination. We expect this proposal to have no impact on information collection burden for the Hospital OQR Program because this policy does not require hospitals to submit new data to CMS. With respect to any costs unrelated to data submission, although this finalized proposal will require some investment in systems updates, the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs) previously finalized a requirement that hospitals use the 2015 Edition Cures Update for eCQMs (85 FR 84818 through 84825). Because all hospitals participating in the Hospital OQR Program are subsection (d) hospitals that also participate in the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs), we do not anticipate any additional costs as a result of this finalized proposal. This is because the burden and costs involved in updating to the 2015 Edition Cures Update is the same regardless of whether the technology is used for eCQMs. Therefore, we believe that the Medicare Promoting Interoperability Program has already addressed the additional costs unrelated to data submission through their previously finalized requirements.

In section XV.D.9.c. of this proposed rule, we are proposing to reduce the number of days hospitals have to submit medical records to the CDAC from 45 days to 30 days. In previous years, charts were requested by the CMS CDAC contractor and hospitals were given 45 days from the date of the request to submit the requested records. This may be an additional administrative burden to hospitals selected for validation. However, this deadline is in line with the Hospital IQR Program's validation policy, the large majority of hospitals that have participated in Hospital OQR Program data validation efforts have submitted their records prior to 30 days in the current process, and outpatient records typically contain significantly fewer pages than the inpatient records. Therefore, we believe the impact of this proposal to be minimal.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XVI. of this proposed rule, we discuss our proposed policies affecting the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. For the CY 2021 payment determination, all 6,811 ASCs that met eligibility requirements for the ASCQR Program received the annual payment update due to data submission requirements being excepted under the ASCQR Program's Extraordinary Circumstances Exceptions policy in consideration of the COVID–19 public health emergency.[446]

b. Impact of Proposals in This CY 2022 OPPS/ASC Proposed Rule

In section XVI. of this proposed rule, we propose to: (1) Require four patient safety outcome measures beginning with the CY 2023 reporting period/CY 2025 payment determination: (a) Patient Burn (ASC–1); (b) Patient Fall (ASC–2); (c) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (ASC–3); and (d) All-Cause Hospital Transfer/Admission (ASC–4); (2) require the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC–11) measure, beginning with the CY 2023 reporting period/CY 2025 payment determination; (3) require the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey measures (ASC–15 a–e), with voluntary reporting for the CY 2023 reporting period/CY 2025 payment determination and mandatory reporting beginning with CY 2024 reporting period/CY 2026 payment determination; (4) add two additional data collection survey modes of OAS CAHPS measures collection to the existing three modes of collection and provide survey administration requirements; and (5) adopt the COVID–19 Vaccination Coverage Among HCP measure, beginning with the CY 2022 reporting period/CY 2024 payment determination.

As shown in Table 70 in section XXIII.C.3.e. (Collection of Information), we estimate a total information collection burden increase for 4,646 ACSs of +67,085 hours at a cost of +$2,844,404 annually associated with our proposed policies and updated burden estimates across a 4 year period from the CY 2023 reporting period/CY 2025 payment determination through the CY 2026 reporting period/CY 2028 payment determination, compared to our currently approved information collection burden estimates. We refer readers to section XXIII.C. of the preamble of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the ASCQR Program.

In section XVI.B.3.a. of the preamble of this proposed rule, we are proposing to adopt a COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2022 reporting period/CY 2024 payment determination. The impacts and benefits associated with this proposal are similar to those previously discussed for the same measure being proposed for the Hospital OQR Program. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act

[446] Centers for Medicare & Medicaid Services. COVID–19 Quality Reporting Programs Guidance Memo. Available at *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

(NCVIA).[447] Although the burden associated with the COVID–19 Vaccination Coverage Among HCP measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666, the cost and burden information is included here. We estimate that each ASC will spend on average approximately 1 hour per month to collect data for the COVID–19 Vaccination Coverage Among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe an Administrative Assistant would spend between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. Beginning with the CY 2022 reporting period/FY 2024 payment determination, ASCs would incur an additional annual burden between 9 hours (0.75 hours/month × 12 months) and 15 hours (1.25 hours/month × 12 months) per ASC and between 41,814 hours (9 hours/hospital × 4,646 ASCs) and 69,690 hours (15 hours/hospital × 4,646 ASCs) for all ASCs. Each ASC would incur an estimated cost of between $323.28 (9 hours × $35.92/hour) and $538.80 annually (15 hours × $35.92/hour). The estimated cost across all 4,646 ASCs would be between $1,501,959 ($323.28/ASC × 4,646 ASCs) and $2,503,265 ($538.80/ASC × 4,646 ASCs) annually thereafter. We welcome comments on the estimated time to collect data and enter it into the NHSN as well as any additional costs associated with this measure.

We anticipate that the proposals affecting the ASCQR Program in this proposed rule may impact the number of ASCs that will receive payment reductions.

6. Effects of Requirements for the RO Model

a. Financial Impact

We have examined the impact of this proposed rule as required by Executive Order 12866 and other laws and Executive Orders, requiring economic analysis of the effects of final rules. We are proposing a different Model performance period than was finalized in the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs final rule with comment period (CMS–1736–IFC) (85 FR 85866) (hereinafter referred to as ''CY 2021 OPPS/ASC final rule''). We are also proposing an updated baseline period, lower discounts, the removal of brachytherapy from the included modalities, and the removal of liver cancer from the list of included cancer types finalized under the publication of the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures Final Rule (Specialty Care Models final rule) (85 FR 61114) on September 29, 2020. We have updated our net estimate of the RO Model impact to reflect all of the proposals in this proposed rule. Accordingly, we have prepared an RIA that, to the best of our ability, reflects the economic impact of the policies contained in this proposed rule.

b. Statement of Need for the Radiation Oncology (RO) Model

The statement of need for the RO Model described in the Specialty Care Models final rule (85 FR 61347) and the CY 2021 OPPS/ASC final rule (85 FR 86296) remains unchanged with this proposed rule.

c. Impact of RO Model

Based on the finalized policy of the Specialty Care Models final rule (85 FR 61114), we expected a savings of $230 million for Medicare over a 5-year model performance period. The CY 2021 OPPS/ASC final rule (85 FR 86296) included a savings estimate of $220 million for Medicare over a 4.5-year model performance period. We now expect that the proposals included in this proposed rule, which include a change to a revised model performance period that begins January 1, 2022 and ends December 31, 2026, a revised baseline period, the removal of brachytherapy and liver cancer, as well as the lowered discounts, will reduce savings to $160 million for Medicare.

d. Anticipated Effects

(1) Scale of the Radiation Oncology (RO) Model

Revising the model performance period to begin January 1, 2022 would not affect the number of PGPs or HOPDs we expect to furnish RT services in the simulated selected CBSAs. We currently expect the model performance period that begins January 1, 2022, and ends December 31, 2026, will include approximately 282,000 episodes, 250,000 beneficiaries, and $4.6 billion in total episode spending of allowed charges over the Model performance period. The revision is primarily the result of updated FFS Part B enrollment projections, slower assumed growth in RT episodes per patient, and minor technical changes to the projection process.

(2) Effects of the RO Model on the Medicare Program

(a) Overview

Under the current FFS payment system, RT services are paid on a per service basis to both PGPs (including freestanding radiation therapy centers) and HOPDs through the PFS and the OPPS, respectively. The RO Model would be a mandatory model designed to test a prospectively determined episode payment for RT services furnished to Medicare beneficiaries during episodes initiated between January 1, 2022, and December 31, 2026.

(b) Data and Methods

Similar to the analysis performed for the regulatory impact analysis for the Specialty Care Models final rule (85 FR 61347) and the CY 2021 OPPS/ASC final rule (85 FR 86296), a stochastic simulation based on the policies in this proposed rule was created to estimate the financial impacts of the RO Model relative to baseline expenditures.

(c) Medicare Estimate

Table 78 summarizes the estimated impact of the RO Model with a model performance period that begins January 1, 2022, and ends December 31, 2026. We estimate that on net the Medicare program would save $160 million over the model performance period. As in the Specialty Care Models final rule (85 FR 61350) and the CY 2021 OPPS/ASC final rule (85 FR 86297), this is the net Medicare Part B impact that includes both Part B premium and Medicare Advantage United States Per Capita Costs (MA USPCC) rate financing interaction effects. This estimate excludes changes in beneficiary cost sharing liability to the extent it is not a Federal outlay under the policy.

As codified at § 512.280(d), the APM incentive payment will apply only to the professional episode payment amounts and not the technical episode payment amounts. Moreover, due to the 2-year lag in Quality Payment Program performance and payment periods and quality data reporting starting in 2022, APM incentive payments will only be made during 2024. We are now projecting that 80 percent (down from 83 percent as projected in the Specialty Care Models final rule) of physician participants (measured by unique NPI) would receive the APM incentive payment under the Quality Payment Program for 2022.

[447] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

Complete information regarding the data sources and underlying methodology used to determine amounts for reconciliation were not available at the time of this forecast. Like in the Specialty Care Models final rule, in the case of the incomplete payment withhold, we assume CMS retains payment only in the event that offsetting payment errors were made elsewhere. Moreover, past CMS experience in the and Hospital Value-Based Purchasing (VBP) and Merit-based Incentive Payment System (MIPS) programs that included value-based reporting requirements has shown a low rate of non-compliance on the part of providers and suppliers. Given the limited spending being withheld, scoring criteria, (that is the use of the Aggregate Quality Score (AQS) and its application to the quality withhold, as finalized at 85 FR 61226 through 61231), and specified timeframes involved, we assume that quality and patient experience withholds, on net, would have a negligible financial impact to CMS.

A key assumption underlying the impact estimate is that the volume and intensity (V&I) of the bundled services per episode remains unchanged between the baseline period and when bundled RO payments are made. If V&I were to decrease by 1.0 percent annually for the bundled services absent the RO Model, then we estimate the RO Model to be approximately budget neutral between January 1, 2022 and December 31, 2026. Similarly, if V&I increases by 1.0 percent annually then net Medicare outlays would be reduced by $285 million for this projection period. Although V&I growth from 2014 through 2019 fell within this 1.0 percent range and did not exhibit a secular trend, actual experience may differ. Please also note that due to the current public health crisis caused by the COVID–19 virus, the forecasted impacts for the RO Model are subject to an additional level of uncertainty. The duration of the current COVID–19 pandemic, its severity, and future policy measures taken in response are variables that are significant but unknown at this time. This forecast assumes that Medicare FFS billing and treatment patterns for beneficiaries observed during the 2017 to 2019 baseline period resume by the start of 2022. To the extent that this assumption does not hold, actual experience may vary significantly. Table 78 summarizes our estimated impacts of this proposed rule.

TABLE 78: Estimates of Medicare Program Savings (Millions $) for Radiation Oncology Model (Starting January 1, 2022)

	Year of Model					
	2022	2023	2024	2025	2026	Total*
Net Impact To Medicare Program Spending	-20	-30	-20	-40	-40	-160
Changes to Incurred FFS Spending	-20	-20	-30	-30	-30	-130
Changes to MA Capitation Payments	-10	-20	-20	-20	-30	-100
Part B Premium Revenue Offset	10	10	10	10	10	60
Total APM Incentive Payments	0	0	10	0	0	10
Episode Allowed Charges	830	870	910	960	1,000	4,580
Episode Medicare Payment	650	680	710	750	780	3,570
Total Number of Episodes	53,300	54,900	56,400	58,000	59,600	282,200
Total Number of Beneficiaries	51,900	53,500	54,900	56,500	58,100	250,200

*Negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase.

*Totals may not sum due to rounding and from beneficiaries that have cancer treatment spanning multiple years.

e. Effects on RO Participants

We believe that the proposed changes will not affect the total cost of learning the billing system for the RO Model but will, however, affect the burden estimate for reporting quality measures and clinical data elements.

We believe the burden estimate for quality measure and clinical data element reporting requirements that is provided for Small Businesses in CY 2021 OPPS/ASC final rule (85 FR 86297) apply to RO participants that are not considered small entities. The burden estimate for collecting and reporting quality measures and clinical data for the RO Model may be equal to or less than that for small businesses, which we estimate to be approximately $1,845 per entity per year based on 2020 wages. Since we estimate approximately 500 Professional participants and Dual participants will be collecting and reporting this data, the total annual burden estimate for collecting and reporting quality measures and clinical data is approximately $922,500 for a total of $4,612,500 over 5 years.

f. Regulatory Flexibility Act (RFA)

In the Medicare Specialty Models final rule, we provided an analysis for the RO Model's impact on small businesses based on the finalized policies (85 FR 61358). The policies proposed in this proposed rule do not change those estimates.

Like the Medicare Specialty Models final rule (85 FR 61358), this proposed rule affects: (1) Radiation oncology PGPs that furnish RT services in both freestanding radiation therapy centers and HOPDs; (2) PGPs that furnish RT

services only in HOPDs; (3) PGPs that are categorized as freestanding radiation therapy centers; and (4) HOPDs. Based on the proposed modifications to the design of the RO Model, we believe that on average, Medicare FFS payments to PGPs will increase by 5.5 percent and Medicare FFS payments to HOPDs will be reduced by 9.6 percent over the life of the Model. Under Medicare FFS, PGPs are largely paid through the PFS for RT services while HOPDs are paid through the OPPS. Unit-cost increases under the PFS are projected to be lower than under the OPPS over time. This means that when the payment rates of the PFS and the OPPS (along with the volume of HCPCS codes of non-participant episodes) are used to determine the trend factors for each cancer type, PGPs, on average, are projected to experience incremental gains to payment over time, while HOPDs, on average, are projected to experience incremental losses to payment over time. In other words, the impact for HOPDs and PGPs depends on a combination of the RO Model's discount factor and the RO Model's trend factor, which blends the latest OPPS and PFS payment rates based on their historical claims volume in non-participating RT providers and RT suppliers. Given that PFS rates are not expected to increase between 2019 and 2026 and the OPPS rates are, blending these rates together leads to an average increase in allowed charges expected for PGPs and an average decrease in allowed charges expected for HOPDs (because HOPDs that are RO participants will not get the full OPPS rate increase but rather a trend that blends OPPS with PFS). Table 79 provides additional information about the expected impacts by year:

TABLE 79: Radiation Oncology Model PGP vs HOPD Allowed Charge Impacts 2022 to 2026

% Impact	2022	2023	2024	2025	2026	2022 to 2026
PGP	1.8%	3.5%	5.2%	6.8%	8.5%	5.5%
HOPD	-7.2%	-8.3%	-9.3%	-10.4%	-11.3%	-9.6%

We believe that this impact would be reduced for smaller RO participants, those RO participants that are eligible for the low volume opt-out in some performance years, and that there would be no impact for those RO participants that are eligible for the low volume opt-out for the entire model performance period (See section XVIII.C.3.d.).

7. Effects of Requirements for Hospitals To Make Public a List of Their Standard Charges

In this proposed rule, we are proposing a modification to 45 CFR 180.30(b) and adding new § 180.30(b)(3) to include that State forensic hospitals will deemed to have met requirements, similar to our policy to deem Federally owned/operated hospitals as having met compliance. These State forensic hospitals and have closed populations, are not open to the general public, and the cost of care is funded by the state. This proposal will reduce the overall burden we estimated in the Hospital Price Transparency final rule by removing such hospitals from the obligation to make public standard charges in the form and manner prescribed by the Secretary.

In the Hospital Price Transparency final rule, we estimated the total burden for hospitals to review and post their standard charges for the first year to be 150 hours per hospital at $11,898.60 per hospital for a total burden of 900,300 hours (150 hours × 6,002 hospitals) and total cost of $71,415,397 ($11,898.60 × 6,002 hospitals) (84 FR 65595). We estimated the total annual burden for hospitals to review and post their standard charges for subsequent years to be 46 hours per hospital at $3,610.88 per hospital for a total annual burden for subsequent years of 276,092 hours (46 hours × 6,002 hospitals) and total annual cost of $21,672,502 ($3,610.88 × 6,002 hospitals). For purposes of the proposed changes in this rule, we assume that state forensic hospitals have complied with the Hospital Price Transparency final rule requirements in the first year of implementation (CY 2021) and are therefore basing our burden reduction estimate on the cost of implementation for subsequent years alone. In other words, because state forensic hospitals would no longer be required to make the annual updates as required under the Hospital Price Transparency final rule, the burden reduction applies to CY 2022 and subsequent years.

We estimate that 111 [448] hospitals would meet our definition of 'State forensic hospital'. To estimate the associated burden reduction for State forensic hospitals, we used the hourly cost for each labor category by referencing Bureau of Labor Statistics report on Occupational Employment and Wages (May 2020), as indicated in Table 80.[449]

[448] SAMHSA. National Mental Health Services Survey (N–MHSS): 2019 Data on Mental Health Treatment Facilities. *https://www.samhsa.gov/data/sites/default/files/reports/rpt29388/2019_NMHSS/2019–NMHSS–R.pdf.*

[449] Bureau of Labor Statistics. National Occupational Employment and Wage Estimates, May 2020. Available at *https://www.bls.gov/oes/current/oes_nat.htm.*

TABLE 80: Occupation Titles and Wage Rates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
General Operations Manager	11-1021	$60.45	$60.45	$120.90
Business Operations Specialist	13-1000	$37.66	$37.66	$75.32
Network and Computer System Administrator	15-1244	$43.01	$43.01	$86.02

We estimate a reduction in burden of 2 hours for a general operations manager to review and determine updates in compliance requirements, or a savings of $241.80 (2 hours * $120.90) per hospital. We estimate a total burden reduction of 222 hours (2 hours * 111 hospitals) with a total burden reduction $26,839.80 (222 hours * $120.90).

Next, we estimate a reduction in burden of 32 hours for a business operations specialist because they will no longer be required to update necessary processes and procedures and gather and compile required information, a savings of $2,410.24 (32 hours * $75.32) per hospital. We estimate a total burden reduction of 3,552 hours (32 hours * 111 hospitals) with a total burden reduction $267,536.64 (3,552 hours * $75.32).

Finally, we estimate a reduction in burden of 12 hours for network and computer system administrator because they will no longer be required to maintain the required systems to make this data publicly available, a savings of $1,032.24 (12 hours * $86.02) per hospital. We estimate a total burden reduction of 1,332 hours (12 hours * 111 hospitals) with a total burden reduction $114,578.64 (1,332 hours * $86.02).

Therefore, we believe the total annual burden reduction for the proposal in this rule, for subsequent years, to be 46 hours (2 hours + 32 hours + 12 hours) per hospital, with a savings of $3,684.28 ($241.80 + $2,410.24 + $1,032.24) per hospital. We also estimate a total annual burden reduction for subsequent years of 5,106 hours (46 hours * 111 hospitals) and a total cost of $408,955.08 ($3,684.28 * 111 hospitals), as shown in Table 81.

TABLE 81: Costs per Organization and Total Cost Figures

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)	Subsequent Year Hours
General Operations Manager	11-1021	$60.45	$60.45	$120.90	2
Business Operations Specialist	13-1000	$37.66	$37.66	$75.32	32
Network and Computer System Administrator	15-1244	$43.01	$43.01	$86.02	12
Total Hours per State forensic hospital					46
Total Reduction per state forensic hospital (Dollars)					($3,684.28)
Total hours for State forensic hospitals (hours)					5,106
Total Burden Reduction for all State forensic hospitals					($408,955.08)

D. 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 this CY 2022 OPPS/ASC proposed rule (1,349) will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing proposed rule. It is possible that not all commenters will review the proposed rule in detail, and it is also possible that some reviewers will choose not to comment on the proposed rule. Nonetheless, we believe that the number of commenters on the CY 2022 OPPS/ASC proposed rule is a fair estimate of the number of reviewers of the proposed rule. We welcome 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 the 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.

Using the wage information from the 2019 BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rule is $110.74 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 proposed rule. For each facility that reviewed the proposed rule, the estimated cost is $885.92 (8 hours × $110.74). Therefore, we estimated that the total cost of reviewing the proposed rule is

$1,195,106 ($885.92 × 1,349 reviewers on the CY 2022 proposed rule).

E. 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, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 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 $16.5 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*. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule. As a result, the Secretary has determined that this proposed rule will not have a significant impact on a substantial number of small entities.

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 604 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 proposed rule would increase payments to small rural hospitals by approximately 3 percent; therefore, it should not have a significant impact on approximately 586 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

F. 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. In 2021, that threshold level is currently approximately $175 million. This proposed rule does not mandate any requirements for state, local, or tribal governments, or for the private sector.

G. Conclusion

The changes we are making in this proposed rule 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 2022. Table 71 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 1.8 percent increase in payments for all services paid under the OPPS in CY 2022, 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, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2022.

The updates we propose to the ASC payment system for CY 2022 would affect each of the approximately 5,600 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would 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 72 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.3 percent for CY 2022.

H. 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 proposed rule 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 71 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including state and local governmental hospitals) will increase by 2.3 percent under this proposed rule. 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 proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule 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.

I, Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 16, 2021.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

45 CFR Part 180

Hospitals, Reporting and recordkeeping requirements.

Centers for Medicare & Medicaid Services

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.3 is amended by revising paragraph (d)(2)(i) to read as follows:

§ 412.3 Admissions.

* * * * *

(d) * * *

(2) * * *

(i) For those services and procedures removed on or after January 1, 2020, the exemption in this paragraph (d)(2) will last for 2 years from the date of such removal.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 4. Section 416.164 is amended by revising paragraphs (a)(4) and (b)(6) to 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 and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174;

* * * * *

(b) * * *

(6) Non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174.

* * * * *

■ 5. Section 416.166 is revised to read as follows:

§ 416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* Effective for services furnished on or after January 1, 2022, covered surgical procedures are those procedures that meet the general standards described in paragraph (b) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section.

(b) *General standards.* Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary 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.

(c) *General exclusions.* Notwithstanding paragraph (b) of this section, covered surgical procedures do not include those surgical procedures that—

(1) Generally result in extensive blood loss;

(2) Require major or prolonged invasion of body cavities;

(3) Directly involve major blood vessels;

(4) Are generally emergent or life-threatening in nature;

(5) Commonly require systemic thrombolytic therapy;

(6) Are designated as requiring inpatient care under § 419.22(n) of this chapter;

(7) Can only be reported using a CPT unlisted surgical procedure code; or

(8) Are otherwise excluded under § 411.15 of this chapter.

(d) *Additions to the list of ASC covered surgical procedures.* Surgical procedures are added to the list of ASC covered surgical procedures as follows:

(1) *Nominations.* On or after January 1, 2023, an external party may nominate a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year.

(2) *Inclusion in rulemaking.* If CMS identifies a surgical procedure that meets the requirements at paragraph (a) of this section, including a surgical procedure nominated under paragraph (d)(1) of this section, it will propose to add the surgical procedure to the list of ASC covered surgical procedures in the next available annual rulemaking.

■ 6. Section 416.171 is amended by revising paragraphs (b)(1) and (4) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

* * * * *

(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 and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174.

* * * * *

(4) Notwithstanding paragraph (b)(2) of this section, procedures assigned to Low Volume APCs where the otherwise applicable payment rate calculated based on the standard methodology for such procedures described in paragraph (b) of this section would exceed the payment rate for the equivalent service set under the payment system established under part 419 of this chapter, for which the payment rate will be set at an amount equal to the amount under that payment system.

* * * * *

■ 7. Section 416.174 is added to reads as follows:

§ 416.174 Payment for non-opioid pain management drugs and biologicals that function as supplies in surgical procedures.

(a) *Eligibility for separate payment for non-opioid pain management drugs and biologicals.* Beginning on or after January 1, 2022, a non-opioid pain management drug or biological that functions as a surgical supply is eligible for separate payment if CMS determines it meets the following requirements:

(1) The drug is approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), generic drug application under an abbreviated new drug application under section 505(j), or, in the case of a biological product, is licensed under section 351 of the Public Health Service Act. The product has an FDA approved indication for pain management or analgesia.

(2) The per-day cost of the drug or biological must exceed the OPPS drug packaging threshold set annually through notice and comment rulemaking.

(b) [Reserved]

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 8. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 9. Section 419.22 is amended by revising paragraph (n) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(n) Services and procedures that the Secretary designates as requiring inpatient care.

* * * * *

■ 10. Section 419.23 is added to read as follows:

§ 419.23 Removal of services and procedures from the Inpatient Only List.

(a) *Inpatient Only List.* CMS maintains a list of services and procedures that the Secretary designates as requiring inpatient care under § 419.22(n) that are not paid under the hospital outpatient prospective payment system. This list is referred to as the Inpatient Only List.

(b) *Removals from the Inpatient Only List.* CMS assesses annually whether a service or procedure on the Inpatient Only List described in paragraph (a) of this section should be removed from the list by determining whether the service or procedure meets at least one of the following criteria:

(1) Most outpatient departments are equipped to provide the service or procedure to the Medicare population.

(2) The simplest service or procedure described by the code may be performed in most outpatient departments.

(3) The service or procedure is related to codes that CMS has already removed from the Inpatient Only List described in paragraph (a) of this section.

(4) CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.

(5) CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center, and is specified as a covered ambulatory surgical procedure under § 416.166 of this chapter, or CMS has proposed to specify it as a covered ambulatory surgical procedure under § 416.166 of this chapter.

■ 11. Section 419.46 is amended by revising paragraphs (f)(1) and (3) to read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(f) * * *

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS supporting medical record documentation that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the supporting medical record documentation to CMS or its contractor within 30 days of the date identified on the written request, in the form and manner specified in the written request.

* * * * *

(3) CMS will select a random sample of 450 hospitals for validation purposes, and will select an additional 50 hospitals for validation purposes based on the following criteria:

(i) The hospital fails the validation requirement that applies to the previous year's payment determination; or

(ii) The hospital has an outlier value for a measure based on the data it submits. An ''outlier value'' is 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; or

(iii) Any hospital that has not been randomly selected for validation in any of the previous 3 years; or

(iv) Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.

* * * * *

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 12. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 13. Section 512.205 is amended by:

■ a. Adding the definition for ''Baseline period'' in alphabetical order;

■ b. Revising the definition for ''Discount factor'';

■ c. Adding definitions for ''EUC'', ''Legacy CCN'', and ''Legacy TIN'' in alphabetical order;

■ d. Revising the definition for ''Model performance period'';

■ e. Removing the definition of ''Performance year (PY)'';

■ f. Revising the definition for ''PY'' and ''Stop-loss reconciliation amount''; and

■ g. Adding definitions for ''Track One'' and ''Track Two'' in alphabetical order.

The additions and revisions read as follows:

§ 512.205 Definitions.

* * * * *

Baseline period means the three calendar year period that begins on January 1 no fewer than five years but no more than six years prior to the start of the model performance period during which episodes must initiate in order to be used in the calculation of the national base rates, each RO participant's historical experience adjustment for the PC or TC or both for the model performance period, and the RO participant's case mix adjustment for the PC or TC or both for PY1. The baseline period is January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in calendar year (CY) 2022, in which case the baseline period will be delayed based on the new model performance period (for example, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

* * * * *

Discount factor means the percentage by which CMS reduces payment of the professional component and technical component.

(1) The reduction of payment occurs after the trend factor, the geographic adjustment, and the RO Model-specific adjustments have been applied, but before beneficiary cost-sharing and standard CMS adjustments, including sequestration, have been applied.

(2) The discount factor does not vary by cancer type.

(3) The discount factor for the professional component is 3.5 percent; the discount factor for the technical component is 4.5 percent.

* * * * *

EUC stands for ''extreme and uncontrollable circumstance'' and means a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale.

* * * * *

Legacy CCN means a CMS certification number (CCN) that an RO participant that is a hospital outpatient department (HOPD) or its predecessor(s) previously used to bill Medicare for included radiotherapy (RT) services but no longer uses to bill Medicare for included RT services.

Legacy TIN means a taxpayer identification number (TIN) that an RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s) previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services.

* * * * *

Model performance period means the five performance years (PYs) during which RO episodes must initiate and terminate. The model performance period begins on January 1, 2022 and ends on December 31, 2026, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period begins on the earliest date permitted by law that is January 1, April 1, or July 1.

* * * * *

PY stands for performance year and means each 12-month period beginning on January 1 and ending on December 31 during the model performance

period, unless the model performance period begins on a date other than January 1, in which case, the first performance year (PY1) begins on that date and ends on December 31 of the same year.

* * * * *

Stop-loss reconciliation amount means the amount set forth in § 512.285(f) owed by CMS for the loss incurred under the Model to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

* * * * *

Track One means an Advanced APM and MIPS APM track for Dual participants and Professional participants that meet all RO Model requirements as specified in § 512.220, including use of CEHRT.

Track Two means an APM for Dual participants and Professional participants who do not meet the RO Model requirements set forth at § 512.220; and for all Technical participants.

* * * * *

■ 14. Section 512.210 is amended by—

■ a. Revising paragraphs (a) and (b)(5).

■ b. Adding paragraph (b)(6);

■ c. Revising paragraph (c); and

■ d. Adding paragraph (e).

The revisions and additions read as follows:

§ 512.210 RO participants and geographic areas.

(a) *RO participants.* Unless otherwise specified in paragraph (b) or (c) of this section, any Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that furnishes included RT services in a 5-digit ZIP Code linked to a CBSA selected for participation to an RO beneficiary for an RO episode that begins and ends during the model performance period must participate in the RO Model.

(b) * * *

(5) Participates in the Pennsylvania Rural Health Model; or

(6) Participates in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model as a participating hospital.

(c) *Low volume opt-out.* A PGP, freestanding radiation therapy center, or HOPD that would otherwise be required to participate in the RO Model may choose to opt-out of the RO Model as follows:

(1) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 episodes in the calendar year that is two years prior to the start of PY1 across all CBSAs selected for participation, it may opt out of the RO Model for PY1.

(2) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 episodes in the calendar year that is two years prior to the start of PY2 across all CBSAs selected for participation, it may opt out of the RO Model for PY2.

(3) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY1 across all CBSAs selected for participation, and PY1 begins on January 1, it may choose to opt out of the RO Model for PY3. In the event that PY1 begins on a date other than January 1, the PGP, freestanding radiation therapy center, or HOPD may opt-out of the RO Model for PY3 if the total number of furnished episodes of the calendar year in which PY1 began and RO episodes in PY1 is fewer than 20 across all CBSAs selected for participation.

(4) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY2 across all CBSAs selected for participation, it may opt out of the RO Model for PY4.

(5) If the PGP, freestanding radiation therapy center, or HOPD furnished fewer than 20 RO episodes in PY3 across all CBSAs selected for participation, it may opt out of the RO Model for PY5.

(6) At least 30 days prior to the start of each PY, CMS provides notice to RO participants eligible for the low volume opt-out for the upcoming PY of such eligibility. The RO participant must attest that it intends to opt out of the RO Model prior to the start of the upcoming PY.

(7) An entity is not eligible for the low-volume opt out if its current TIN or CCN, or its legacy TIN or legacy CCN, or both were used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in the two years prior to the applicable PY across all CBSAs selected for participation.

* * * * *

(e) *Notice of change in TIN or CCN.* An RO participant must furnish written notice to CMS in a form and manner specified by CMS at least 90 days before the effective date of any change in TIN or CCN that is used to bill Medicare.

■ 15. Section 512.217 is amended—

■ a. By revising paragraphs (a), (b), and (c)(1);

■ b. In paragraph (c)(3)(i) by removing the word ''and'' at the end of the paragraph;

■ c. In paragraph (c)(3)(ii) by removing the period at the end of the paragraph and adding ''; and'' in its place;

■ d. By adding paragraph (c)(3)(iii); and

■ e. By revising paragraphs (d)(1)(i) and (d)(2)(i).

The revisions and addition read as follows:

§ 512.217 Identification of individual practitioners.

(a) *General.* Upon the start of each PY, CMS creates and provides to each RO participant that is a PGP or a freestanding radiation therapy center an individual practitioner list identifying by NPI each individual practitioner associated with the RO participant. For RO participants that begin participation in the RO Model after the start of a PY, but at least 30 days prior to the last QP determination date as specified at § 414.1325 of this chapter, CMS creates and provides an individual practitioner list to that RO participant.

(b) *Review of individual practitioner list.* Up until the last QP determination date as specified at § 414.1325 of this chapter, the RO participant must review and certify the individual practitioner list, correct any inaccuracies in accordance with paragraph (d) of this section, and certify the list (as corrected, if applicable) in a form and manner specified by CMS and in accordance with paragraph (c) of this section. The RO participant may correct any inaccuracies in their individual practitioner list until the last QP determination date as specified at § 414.1325 of this chapter. Any Dual participant, Professional participant, or Technical participant that is a freestanding radiation therapy center and joins the RO Model after the start of a PY must review and certify its individual practitioner list by the last QP determination date as specified at § 414.1325 of this chapter.

(c) * * *

(1) Up until the last QP determination date as specified at § 414.1325 of this chapter, an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the individual practitioner list to the best of his or her knowledge, information, and belief.

* * * * *

(3) * * *

(iii) Technical participants that are freestanding radiation therapy centers are not eligible to receive Improvement Activity credit for their participation in the RO Model under MIPS.

(d) * * *

(1) * * *

(i) An RO participant must notify CMS of an addition to its individual practitioner list when an eligible clinician reassigns his or her rights to receive payment from Medicare to the RO participant. The notice must be submitted in the form and manner specified by CMS up until the last QP determination date as specified at § 414.1325 of this chapter.

* * * * *

(2) * * *

(i) An RO participant must notify CMS when an individual on the RO participant's individual practitioner list ceases to be an individual practitioner up until the last QP determination date as specified at § 414.1325 of this chapter. The notice must be submitted in the form and manner specified by CMS.

* * * * *

■ 16. Section 512.220 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 512.220 RO participant compliance with RO Model requirements.

(a) * * *

(1) RO participants must satisfy the requirements of this section to be included in Track One under the RO Model. RO participants that do not meet these RO Model requirements in a PY will be in Track Two for the applicable PY.

* * * * *

(b) *CEHRT.* (1) RO participants must use CEHRT, and ensure that their individual practitioners use CEHRT, in a manner sufficient to meet the applicable requirements of the Advanced APM criteria as specified at § 414.1415(a)(1)(i) of this chapter.

(2) Within 30 days of the start of PY1 and each subsequent PY, the RO participant must certify its use of CEHRT throughout such PY in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

(3) An RO participant that joins the RO Model at any time during an ongoing PY must certify their use of CEHRT by the last QP determination date as specified at § 414.1325 of this chapter.

■ 17. Section 512.230 is amended by revising paragraphs (a) and (b) to read as follows:

§ 512.230 Criteria for determining cancer types.

(a) *Included cancer types.* CMS includes in the RO Model cancer types that satisfy the following criteria:

(1) The cancer type is commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines;

(2) The cancer type has one or more associated current ICD–10 codes that have demonstrated pricing stability; and

(3) The Secretary has not determined that the cancer type is not suitable for inclusion in the RO Model.

(b) *Removing cancer types.* CMS removes cancer types in the RO Model if it determines:

(1) That there is a ≥10 percent error in established national base rates; or

(2) The cancer type does not meet the criteria set forth in paragraph (a) of this section.

* * * * *

■ 18. Section 512.240 is revised to read as follows:

§ 512.240 Included modalities.

The modalities included in the RO Model are 3-dimensional conformal RT (3DCRT), intensity-modulated RT (IMRT), stereotactic radiosurgery (SRS), stereotactic body RT (SBRT), proton beam therapy (PBT), and image-guided radiation therapy (IGRT).

■ 19. Section 512.245 is amended by revising paragraph (a) to read as follows:

§ 512.245 Included RO episodes.

(a) *General.* Any RO episode that begins on or after the first day of the model performance period and ends on or before the last day of the model performance period is included in the model performance period.

* * * * *

■ 20. Section 512.250 is amended by revising (b)(1) and (2) to read as follows:

§ 512.250 Determination of national base rates.

* * * * *

(b) * * *

(1) CMS excludes from episode pricing and RO episode pricing any claim containing an RT service furnished:

(i) In Maryland, Vermont, or any of the U.S. Territories;

(ii) In the inpatient setting;

(iii) By an entity classified as an ASC, CAH, or PPS-exempt cancer hospital; or

(iv) By an HOPD participating in the Pennsylvania Rural Health Model at the time the RT service was furnished.

(2) CMS excludes the following episodes from the determination of the national base rates:

(i) Episodes that are not linked to a CBSA selected for participation in the RO Model;

(ii) Episodes that are not attributed to an RT provider or RT supplier;

(iii) Episodes that are not assigned an included cancer type; or

(iv) Episodes for which the total allowed amount for RT services listed on claims used to calculate an episode's payment amount is not greater than $0.

* * * * *

■ 21. Section 512.255 is amended by—

■ a. Revising paragraphs (c)(7), (8), and (10), (c)(12)(iv), and (c)(13); and

■ b. Adding paragraph (c)(14).

The revisions and addition read as follows:

§ 512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

* * * * *

(c) * * *

(7) *Adjustments for RO participants with fewer than 60 episodes during the baseline period.* (i) RO participants that have fewer than 60 episodes in the baseline period do not receive a historical experience adjustment during the model performance period.

(ii) RO participants that have fewer than 60 episodes in the baseline period do not receive a case mix adjustment for PY1.

(iii) RO participants described in paragraph (c)(7)(ii) of this section that continue to have fewer than 60 episodes in the rolling 3-year period used to determine the case mix adjustment for each PY and that have never received a case mix adjustment do not receive a case mix adjustment for that PY.

(iv) RO participants that have fewer than 60 episodes in the baseline period and were furnishing included RT services in the CBSAs selected for participation before the start of the model performance period are eligible to receive a stop-loss reconciliation amount, if applicable, as described in § 512.285(f).

(8) *Discount factor.* CMS reduces each episode payment by the discount factor after applying the trend factor, geographic adjustment, and case mix and historical experience adjustments to the national base rate.

* * * * *

(10) *Quality withhold.* In accordance with § 414.1415(b)(1) of this chapter, CMS withholds 2 percent from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. RO participants may earn back this withhold, in part or in full, based on their AQS.

* * * * *

(12) * * *

(iv) In the case of incomplete episodes, the beneficiary coinsurance payment equals 20 percent of the FFS amounts that would have been paid in the absence of the RO Model for the

services furnished by the RO participant that initiated the PC and the RO participant that initiated the TC (if applicable).

* * * * *

(13) *Sequestration.* In accordance with applicable law, CMS deducts a percentage from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rate.

(14) *Modifications to the participant-specific adjustments for changes in TINs or CCNs.* (i) CMS calculates the RO participant's case mix adjustments in accordance with paragraph (c)(3) of this section based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the 3-year period that determines the case mix adjustment for each PY.

(ii) CMS calculates the RO participant's historical experience adjustments in accordance with paragraph (c)(4) of this section based on all episodes attributed to the RO participant's legacy TIN(s) or legacy CCN(s), and current TIN or CCN, during the baseline period.

■ 22. Section 512.275 is amended by adding paragraph (d) to read as follows:

§ 512.275 Quality measures, clinical data, and reporting.

* * * * *

(d) *Technical participants and reporting of quality measures and clinical data elements.* Technical participants that are freestanding radiation therapy centers and also begin furnishing the professional component during the model performance period must:

(1) Notify CMS within 30 days of when the technical participant begins furnishing the professional component, in a form and manner specified by CMS; and

(2) Must report quality measures and clinical data elements by the next submission period, as described in paragraph (c) of this section.

§ 512.280 [Amended]

■ 23. Section 512.280 is amended by removing and reserving paragraph (f)(4).

■ 24. Section 512.285 is amended by revising paragraphs (c)(3), (c)(4)(i) and (ii), (d), and (f) introductory text to read as follows:

§ 512.285 Reconciliation process.

* * * * *

(c) * * *

(3) *Total incomplete episode amount.* For incomplete episodes initiated in the PY, CMS determines the total incomplete episode amount by calculating the difference between the following amounts:

(i) The sum of all FFS amounts that would have been paid to the RO participant in the absence of the RO Model for any included RT services furnished during such incomplete episodes, as determined by no-pay claims. CMS owes this sum to the RO participant for such incomplete episodes.

(ii) The sum of the participant-specific episode payment amounts paid to the RO participant for such incomplete episodes initiated in the PY.

(4) * * *

(i) If the sum described in paragraph (c)(3)(i) of this section is more than the sum described in paragraph (c)(3)(ii) of this section, the difference is subtracted from the total duplicate RT services amount described in paragraph (c)(2) of this section and the resulting amount is the total incorrect episode payment amount.

(ii) If the sum described in paragraph (c)(3)(i) of this section is less than the sum described in paragraph (c)(3)(ii) of this section, the difference is added to the total duplicate RT services amount described in paragraph (c)(2) of this section and the resulting amount is the total incorrect episode payment amount.

* * * * *

(d) *Quality reconciliation payment amount.* For Professional participants and Dual participants, CMS determines the quality reconciliation payment amount for each PY by multiplying the participant's AQS (as a percentage) by the total quality withhold amount for all RO episodes initiated during the PY.

* * * * *

(f) *Stop-loss reconciliation amount.* CMS determines the stop-loss reconciliation amount for RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation by—

* * * * *

■ 25. Section 512.292 is added to read as follows:

§ 512.292 Overlap with other models tested under Section 1115A and CMS programs.

Participant-specific professional episode payments and Participant-specific technical episode payments made under the RO Model are not adjusted to reflect payments made under models being tested under 1115A of the Act or the Medicare Shared Savings Program under section 1899 of the Act.

■ 26. Section 512.594 is added to read as follows:

§ 512.294 Extreme and uncontrollable circumstances.

(a) If CMS determines that there is an EUC pursuant to paragraph (b) of this section, CMS may grant RO participants exceptions to the RO Model requirements under paragraph (c) of this section and revise the RO Model's payment methodology under paragraph (d) of this section.

(b) CMS determines whether there is an EUC based on the following factors:

(1) Whether the RO participants are furnishing services within a geographic area considered to be within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Social Security Act;

(2) Whether the geographic area within a county, parish, U.S. territory, or tribal government designated under the Stafford Act served as a condition precedent for the Secretary's exercise of the 1135 waiver authority, or the National Emergencies Act; or

(3) Whether a state of emergency has been declared in the geographic area.

(c) CMS may grant RO Participants exceptions to the following RO Model requirements:

(1) *Reporting requirements.* CMS may delay or exempt RO participants from one or more of the RO Model's quality measure or clinical data element reporting requirements if an EUC impacts the RO participants' ability to comply with quality measure or clinical data element reporting requirements.

(2) *Other requirements.* CMS may issue a notice on the RO Model website that may waive compliance with or modify the following RO Model requirements:

(i) The requirement set forth at § 512.220(a)(2)(vii) that RO participants provide Peer Review (audit and feedback) on treatment plans.

(ii) The requirement set forth at § 512.220(a)(3) that RO participants actively engage with an AHRQ-listed patient safety organization (PSO).

(d) If CMS determines that the EUC affects the United States and if CMS determines that the EUC would impact RO participants' ability to implement the requirements of the RO Model prior to the start of the model performance period, CMS may amend the model performance period. CMS will notify RO participants of such a determination via the RO Model website no later than 30 days prior to the start date of the model performance period.

(e) If CMS determines that the EUC affects the entire United States, and if CMS determines that as a result of the EUC, the trend factor (specific to the PC, TC, or both for an included cancer type) for the upcoming PY has increased or decreased by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payment rates are held constant with the previous CY, CMS may modify the trend factor calculation for the PC, TC, or both the PC and TC of an included cancer type in a manner that ensures the trend factor is consistent with the average utilization from the previous CY.

(f) In response to a national, regional, or local event, CMS may adjust the quality withhold by choosing to repay the quality withhold during the next reconciliation, and award all possible points in the subsequent AQS calculation amount if CMS removes the quality measure and clinical data element reporting requirements pursuant to paragraph (c)(1) of this section.

Department of Health and Human Services

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 180 as set forth below:

PART 180—HOSPITAL PRICE TRANSPARENCY

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

Authority: 42 U.S.C. 300gg–18, 42 U.S.C. 1302.

■ 28. Section 180.20 is amended by adding a definition for ''State forensic hospital'' in alphabetical order to read as follows:

§ 180.20 Definitions.

* * * * *

State forensic hospital means a public psychiatric hospital that provides treatment for individuals who are in the custody of penal authorities.

* * * * *

■ 29. Section 180.30 is amended—

■ a. In paragraph (b) introductory text by removing the phrase ''Federally owned or operated hospitals'' and adding in its place the phrase ''Federal and State hospitals''; and

■ b. By adding paragraph (b)(3).

The addition reads as follows:

§ 180.30 Applicability.

* * * * *

(b) * * *

(3) State forensic hospitals that provide treatment exclusively to individuals who are in the custody of penal authorities.

* * * * *

■ 30. Section 180.50 is amended—

■ a. In paragraph (d)(3)(ii) by removing the word ''and'' at the end of the paragraph;

■ b. In paragraph (d)(3)(iii) by removing the period at the end of the paragraph and adding ''; and'' in its place; and

■ c. By adding paragraph (d)(3)(iv).

The addition reads as follows:

§ 180.50 Requirements for making public hospital standard charges for all items and services.

* * * * *

(d) * * *

(3) * * *

(iv) To automated searches and direct file downloads through a link posted on a publicly available website.

* * * * *

■ 31. Section 180.90 is amended by revising paragraph (c)(2) to read as follows:

§ 180.90 Civil monetary penalties.

* * * * *

(c) * * *

(2) CMS determines the daily dollar amount for a civil monetary penalty for which a hospital may be subject as follows:

(i) For each day during Calendar Year 2021 that a hospital is determined by CMS to be out of compliance, the maximum daily dollar amount for a civil monetary penalty to which the hospital may be subject is $300. Even if the hospital is in violation of multiple discrete requirements of this part, the maximum total sum that a single hospital may be assessed per day is $300.

(ii) Beginning January 1, 2022, for each day a hospital is determined by CMS to be out of compliance:

(A) For a hospital with a number of beds equal to or less than 30, the maximum daily dollar civil monetary penalty amount to which it may be subject is $300, even if the hospital is in violation of multiple discrete requirements of this part.

(B) For a hospital with a number of beds between 31 and 550, the maximum daily dollar civil monetary penalty amount to which it may be subject is the number of beds times $10, even if the hospital is in violation of multiple discrete requirements of this part.

(C) For a hospital with a number of beds greater than 550, the maximum daily dollar civil monetary penalty amount to which it may be subject is $5,500, even if the hospital is in violation of multiple discrete requirements of this part.

(D)(*1*) CMS will use the most recently available, finalized Medicare hospital cost report to determine the number of beds for a Medicare-enrolled hospital, for purposes of determining the maximum daily dollar civil monetary penalty amount under paragraph (c)(2) of this section.

(*2*) If the number of beds for the hospital cannot be determined according to paragraph (c)(2)(ii)(D)(*1*) of this section, CMS will request that the hospital provide documentation of its number of beds, in a form and manner and by the deadline prescribed by CMS in a written notice provided to the hospital. Should the hospital fail to provide CMS with this documentation in the prescribed form and manner, and by the specified deadline, CMS will impose on the hospital the maximum daily dollar civil monetary penalty amount according to paragraph (c)(2)(ii)(C) of this section.

* * * * *

Dated: July 16, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–15496 Filed 7–19–21; 4:15 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 414

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2022 and Updates to the IRF Quality Reporting Program; Payment for Complex Rehabilitative Wheelchairs and Related Accessories (Including Seating Systems) and Seat and Back Cushions Furnished in Connection With Such Wheelchairs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1748–F, CMS–1687–IFC, and CMS–1738–F]

RIN 0938–AU38, 0938–AT21, and 0938–AU17

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2022 and Updates to the IRF Quality Reporting Program; Payment for Complex Rehabilitative Wheelchairs and Related Accessories (Including Seating Systems) and Seat and Back Cushions Furnished in Connection With Such Wheelchairs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for Federal fiscal year (FY) 2022. As required by statute, this final rule includes the classification and weighting factors for the IRF prospective payment system's case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2022. This final rule also includes updates for the IRF Quality Reporting Program (QRP). In addition, we are finalizing a Medicare provision adopted in an interim final rule with comment period (IFC) issued on May 11, 2018 related to fee schedule adjustments for wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with group 3 or higher complex rehabilitative power wheelchairs as well as changes to the regulations related to the Further Consolidated Appropriations Act, 2020 governing payment for these and other items.

DATES:

Effective date: These regulations are effective on October 1, 2021.

Applicability dates: The updated IRF prospective payment rates are applicable for IRF discharges occurring on or after October 1, 2021, and on or before September 30, 2022 (FY 2022).

FOR FURTHER INFORMATION CONTACT:

Gwendolyn Johnson, (410) 786–6954, for general information.

Catie Cooksey, (410) 786–0179, for information about the IRF payment policies and payment rates.

Kadie Derby, (410) 786–0468, for information about the IRF coverage policies.

Ariel Adams, (410) 786–8571, for information about the IRF quality reporting program.

DMEPOS@cms.hhs.gov or Alexander Ullman, (410) 786–9671, for issues related to the DMEPOS payment policy.

SUPPLEMENTARY INFORMATION:

Availability of Certain Information Through the Internet on the CMS Website

The IRF prospective payment system (IRF PPS) Addenda along with other supporting documents and tables referenced in this final rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS.*

We note that prior to 2020, each rule or notice issued under the IRF PPS has included a detailed reiteration of the various regulatory provisions that have affected the IRF PPS over the years. That discussion, along with detailed background information for various other aspects of the IRF PPS, is now available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS.*

I. Executive Summary

A. Purpose

This final rule updates the prospective payment rates for IRFs for FY 2022 (that is, for discharges occurring on or after October 1, 2021, and on or before September 30, 2022) as required under section 1886(j)(3)(C) of the Social Security Act (the Act). As required by section 1886(j)(5) of the Act, this final rule includes the classification and weighting factors for the IRF PPS's case-mix groups (CMGs) and a description of the methodologies and data used in computing the prospective payment rates for FY 2022. This final rule adds one new measure to the IRF QRP and modifies the denominator for another measure currently under the IRF QRP beginning with the FY 2023 IRF QRP. In addition, this final rule modifies the number of quarters used for publicly reporting certain IRF QRP measures due to the public health emergency (PHE). In this final rule, we summarize comments we sought on the use of Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources® (FHIR)-based standards in post-acute care, specifically the IRF QRP, and on our continued efforts to close the health equity gap. This final rule also finalizes a Medicare provision adopted in an interim final rule with comment period (IFC) published in the May 11, 2018 **Federal Register** entitled ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas'' (83 FR 21912) that excludes the fee schedule amounts for wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with group 3 or higher complex rehabilitative power wheelchairs from adjustments based on information from the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). In response to public comments on the IFC published in the May 11, 2018 **Federal Register**, we are also finalizing an extension of this policy to wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with complex rehabilitative manual wheelchairs in this final rule. In addition, this rule finalizes a Medicare provision that was included in the proposed rule published in the November 4, 2020 **Federal Register** entitled ''Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)'' (85 FR 70358). The provision implements section 106(a) of division N, title I of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, December 20, 2019) by modifying a regulatory definition in order to exclude complex rehabilitative manual wheelchairs and certain other manual wheelchairs and related accessories when furnished in connection with these wheelchairs from the DMEPOS CBP.

B. Summary of Major Provisions

In this final rule, we use the methods described in the FY 2021 IRF PPS final rule (85 FR 48424) to update the prospective payment rates for FY 2022 using updated FY 2020 IRF claims and the most recent available IRF cost report data, which is FY 2019 IRF cost report data. This final rule updates certain requirements for the IRF QRP. In addition, this final rule addresses fee schedule adjustments for wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with Group 3 or higher complex rehabilitative power wheelchairs and complex rehabilitative manual wheelchairs. This final rule also revises the definition of ''item'' under the DMEPOS CBP at 42 CFR 414.402 to exclude complex rehabilitative manual wheelchairs and certain other manual wheelchairs and related accessories from the DMEPOS CBP, as required by section 106(a) of the FCAA.

C. Summary of Impact

TABLE 1: Cost and Benefit

Provision Description	Transfers/Costs
FY 2022 IRF PPS payment rate update	The overall economic impact of this final rule is an estimated $130 million in increased payments from the Federal Government to IRFs during FY 2022.
FY 2022 IRF QRP changes	The overall economic impact of this final rule is an estimated increase in cost to IRFs of $503,100.00 beginning with 2022.
DMEPOS Complex Power Wheelchair Accessories	The overall economic impact of this final rule is an estimated $130 million in increased payments from the Federal Government to DME suppliers from FY 2022 to FY 2026.
DMEPOS Complex Manual Wheelchair	The overall economic impact of this final rule is an estimated $40 million in increased payments from the Federal Government to DME suppliers from FY 2022 to FY 2026

II. Background

A. Statutory Basis and Scope for IRF PPS Provisions

Section 1886(j) of the Act provides for the implementation of a per-discharge PPS for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (collectively, hereinafter referred to as IRFs). Payments under the IRF PPS encompass inpatient operating and capital costs of furnishing covered rehabilitation services (that is, routine, ancillary, and capital costs), but not direct graduate medical education costs, costs of approved nursing and allied health education activities, bad debts, and other services or items outside the scope of the IRF PPS. A complete discussion of the IRF PPS provisions appears in the original FY 2002 IRF PPS final rule (66 FR 41316) and the FY 2006 IRF PPS final rule (70 FR 47880) and we provided a general description of the IRF PPS for FYs 2007 through 2019 in the FY 2020 IRF PPS final rule (84 FR 39055 through 39057).

Under the IRF PPS from FY 2002 through FY 2005, the prospective payment rates were computed across 100 distinct CMGs, as described in the FY 2002 IRF PPS final rule (66 FR 41316). We constructed 95 CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (in some cases, cognitive status and age may not be a factor in defining a CMG). In addition, we constructed five special CMGs to account for very short stays and for patients who expire in the IRF.

For each of the CMGs, we developed relative weighting factors to account for a patient's clinical characteristics and expected resource needs. Thus, the weighting factors accounted for the relative difference in resource use across all CMGs. Within each CMG, we created tiers based on the estimated effects that certain comorbidities would have on resource use.

We established the Federal PPS rates using a standardized payment conversion factor (formerly referred to as the budget-neutral conversion factor). For a detailed discussion of the budget-neutral conversion factor, please refer to our FY 2004 IRF PPS final rule (68 FR 45684 through 45685). In the FY 2006 IRF PPS final rule (70 FR 47880), we discussed in detail the methodology for determining the standard payment conversion factor.

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted prospective payment rates under the IRF PPS from FYs 2002 through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRFs' unadjusted prospective payment rates.

For cost reporting periods that began on or after January 1, 2002, and before October 1, 2002, we determined the final prospective payment amounts using the transition methodology prescribed in section 1886(j)(1) of the Act. Under this provision, IRFs transitioning into the PPS were paid a blend of the Federal IRF PPS rate and the payment that the IRFs would have received had the IRF PPS not been implemented. This provision also allowed IRFs to elect to bypass this blended payment and immediately be paid 100 percent of the Federal IRF PPS rate. The transition methodology expired as of cost reporting periods beginning on or after October 1, 2002 (FY 2003), and payments for all IRFs now consist of 100 percent of the Federal IRF PPS rate.

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting amendments to the FY 2006 IRF PPS final rule (70 FR 57166), we finalized a number of refinements to the IRF PPS case-mix classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements included the adoption of the Office of Management and Budget's (OMB's) Core-Based Statistical Area (CBSA) market definitions; modifications to the CMGs, tier comorbidities; and CMG relative weights, implementation of a new teaching status adjustment for IRFs; rebasing and revising the market basket

index used to update IRF payments, and updates to the rural, low-income percentage (LIP), and high-cost outlier adjustments. Beginning with the FY 2006 IRF PPS final rule (70 FR 47908 through 47917), the market basket index used to update IRF payments was a market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities (IPFs), and long-term care hospitals (LTCHs) (hereinafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). Any reference to the FY 2006 IRF PPS final rule in this final rule also includes the provisions effective in the correcting amendments. For a detailed discussion of the final key policy changes for FY 2006, please refer to the FY 2006 IRF PPS final rule.

The regulatory history previously included in each rule or notice issued under the IRF PPS, including a general description of the IRF PPS for FYs 2007 through 2020, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS.*

In late 2019,[1] the United States began responding to an outbreak of a virus named ''SARS–CoV–2'' and the disease it causes, which is named ''coronavirus disease 2019'' (abbreviated ''COVID–19''). Due to our prioritizing efforts in support of containing and combatting the PHE for COVID–19, and devoting significant resources to that end, we published two interim final rules with comment period affecting IRF payment and conditions for participation. The interim final rule with comment period (IFC) entitled, ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', published on April 6, 2020 (85 FR 19230) (hereinafter referred to as the April 6, 2020 IFC), included certain changes to the IRF PPS medical supervision requirements at 42 CFR 412.622(a)(3)(iv) and 412.29(e) during the PHE for COVID–19. In addition, in the April 6, 2020 IFC, we removed the post-admission physician evaluation requirement at § 412.622(a)(4)(ii) for all IRFs during the PHE for COVID–19. In the FY 2021 IRF PPS final rule, to ease documentation and administrative burden, we also removed the post-admission physician evaluation documentation requirement at 42 CFR 412.622(a)(4)(ii) permanently beginning in FY 2021.

A second IFC entitled, ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' was published on May 8, 2020 (85 FR 27550) (hereinafter referred to as the May 8, 2020 IFC). Among other changes, the May 8, 2020 IFC included a waiver of the ''3-hour rule'' at § 412.622(a)(3)(ii) to reflect the waiver required by section 3711(a) of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, enacted on March 27, 2020). In the May 8, 2020 IFC, we also modified certain IRF coverage and classification requirements for freestanding IRF hospitals to relieve acute care hospital capacity concerns in states (or regions, as applicable) that are experiencing a surge during the PHE for COVID–19. In addition to the policies adopted in our IFCs, we responded to the PHE with numerous blanket waivers [2] and other flexibilities,[3] some of which are applicable to the IRF PPS.

B. Statutory Basis and Scope for DMEPOS Provisions

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, December 8, 2003), requires CMS to implement the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) for contract award purposes in order to furnish certain competitively priced DMEPOS items and services subject to the CBP. Such items and services include:

- Off-the-shelf (OTS) orthotics, for which payment would otherwise be made under section 1834(h) of the Act;
- Enteral nutrients, equipment, and supplies described in section 1842(s)(2)(D) of the Act; and
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

Section 1834(a)(1)(F)(ii) of the Act requires the Secretary to use information on the payment determined under the Medicare DMEPOS CBP to adjust the fee schedule amounts for DME items and services furnished in all non-CBAs on or after January 1, 2016. Section 1834(a)(1)(F)(iii) of the Act requires the Secretary to continue to make these adjustments as additional covered items are phased in under the CBP or information is updated as new CBP contracts are awarded.

Section 2 of the Patient Access and Medicare Protection Act of 2015 (Pub. L. 114–115, December 28, 2015) excluded the accessories furnished in connection with Group 3 complex rehabilitative power wheelchairs from the fee schedule adjustments under section 1834(a)(1)(F)(ii) of the Act from January 1 through December 31, 2016. Congress then extended this exclusion through June 2017 under section 16005 of the 21st Century Cures Act of 2016 (Pub. L. 114–255, December 13, 2016). In June 2017, we elected to continue this policy through program instructions, followed by interim final rule in 2018, entitled ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas'' (83 FR 21912). On April 26, 2021, we announced the continuation of effectiveness of the 2018 interim final rule and the extension of the timeline for publication of the final rule (86 FR 21949).

Section 106(a) of the FCAA excludes complex rehabilitative manual wheelchairs and certain other manual wheelchairs and wheelchair accessories and seat and back cushions when furnished in connection with these wheelchairs from the DMEPOS CBP. Section 106(b) of the FCAA excludes these items from fee schedule adjustments based on information from the DMEPOS CBP through June 30, 2021. We address section 1834(a)(1)(F)(ii) of the Act and payment for these items in this final rule.

We issued a proposed rule on November 4, 2020 (85 FR 70358) to make conforming changes to the regulations to reflect section 106(a) of the FCAA. This rule proposed to revise the definition of ''item'' under the CBP at 42 CFR 414.402 to exclude complex rehabilitative manual wheelchairs and certain other manual wheelchairs and related accessories when furnished in connection with such wheelchairs from the CBP as required by section 106(a) of the FCAA.

[1] Patel A, Jernigan DB. Initial Public Health Response and Interim Clinical Guidance for the 2019 Novel Coronavirus Outbreak—United States, December 31, 2019—February 4, 2020. MMWR Morb Mortal Wkly Rep 2020;69:140–146. DOI *http://dx.doi.org/10.15585/mmwr.mm6905e1.*

[2] CMS, ''COVID–19 Emergency Declaration Blanket Waivers for Health Care Providers,'' (updated Feb. 19 2021) (available at *https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf*).

[3] CMS, ''COVID–19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing,'' (updated March 5, 2021) (available at *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*).

C. Provisions of the PPACA and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Affecting the IRF PPS in FY 2012 and Beyond

The Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the PPACA, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the ''Patient Protection and Affordable Care Act'' or ''PPACA''.

The PPACA included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was previously discussed, section 3401(d) of the PPACA also added section 1886(j)(3)(C)(ii)(I) of the Act (providing for a ''productivity adjustment'' for FY 2012 and each subsequent FY). The productivity adjustment for FY 2022 is discussed in section VI.B. of this final rule. Section 1886(j)(3)(C)(ii)(II) of the Act provides that the application of the productivity adjustment to the market basket update may result in an update that is less than 0.0 for a FY and in payment rates for a FY being less than such payment rates for the preceding FY.

Sections 3004(b) of the PPACA and section 411(b) of the MACRA (Pub. L. 114–10, enacted on April 16, 2015) also addressed the IRF PPS. Section 3004(b) of PPACA reassigned the previously designated section 1886(j)(7) of the Act to section 1886(j)(8) of the Act and inserted a new section 1886(j)(7) of the Act, which contains requirements for the Secretary to establish a QRP for IRFs. Under that program, data must be submitted in a form and manner and at a time specified by the Secretary. Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the application of a 2 percentage point reduction to the market basket increase factor otherwise applicable to an IRF (after application of paragraphs (C)(iii) and (D) of section 1886(j)(3) of the Act) for a FY if the IRF does not comply with the requirements of the IRF QRP for that FY. Application of the 2 percentage point reduction may result in an update that is less than 0.0 for a FY and in payment rates for a FY being less than such payment rates for the preceding FY. Reporting-based reductions to the market basket increase factor are not cumulative; they only apply for the FY involved. Section 411(b) of the MACRA amended section 1886(j)(3)(C) of the Act by adding paragraph (iii), which required us to apply for FY 2018, after the application of section 1886(j)(3)(C)(ii) of the Act, an increase factor of 1.0 percent to update the IRF prospective payment rates.

D. Operational Overview of the Current IRF PPS

As described in the FY 2002 IRF PPS final rule (66 FR 41316), upon the admission and discharge of a Medicare Part A fee-for-service (FFS) patient, the IRF is required to complete the appropriate sections of a Patient Assessment Instrument (PAI), designated as the IRF–PAI. In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF–PAI upon the admission and discharge of each Medicare Advantage (MA) patient, as described in the FY 2010 IRF PPS final rule (74 FR 39762 and 74 FR 50712). All required data must be electronically encoded into the IRF–PAI software product. Generally, the software product includes patient classification programming called the Grouper software. The Grouper software uses specific IRF–PAI data elements to classify (or group) patients into distinct CMGs and account for the existence of any relevant comorbidities.

The Grouper software produces a five-character CMG number. The first character is an alphabetic character that indicates the comorbidity tier. The last four characters are numeric characters that represent the distinct CMG number. A free download of the Grouper software is available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html.* The Grouper software is also embedded in the internet Quality Improvement and Evaluation System (iQIES) User tool available in iQIES at *https://www.cms.gov/medicare/quality-safety-oversight-general-information/iqies.*

Once a Medicare Part A FFS patient is discharged, the IRF submits a Medicare claim as a Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, enacted on August 21, 1996)-compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (ASCA) (Pub. L. 107–105, enacted on December 27, 2002) permits, a paper claim (a UB–04 or a CMS–1450 as appropriate) using the five-character CMG number and sends it to the appropriate Medicare Administrative Contractor (MAC). In addition, once a MA patient is discharged, in accordance with the Medicare Claims Processing Manual, chapter 3, section 20.3 (Pub. L. 100–04), hospitals (including IRFs) must submit an informational-only bill (type of bill (TOB) 111), which includes Condition Code 04 to their MAC. This will ensure that the MA days are included in the hospital's Supplemental Security Income (SSI) ratio (used in calculating the IRF LIP adjustment) for FY 2007 and beyond. Claims submitted to Medicare must comply with both ASCA and HIPAA.

Section 3 of the ASCA amended section 1862(a) of the Act by adding paragraph (22), which requires the Medicare program, subject to section 1862(h) of the Act, to deny payment under Part A or Part B for any expenses for items or services for which a claim is submitted other than in an electronic form specified by the Secretary. Section 1862(h) of the Act, in turn, provides that the Secretary shall waive such denial in situations in which there is no method available for the submission of claims in an electronic form or the entity submitting the claim is a small provider. In addition, the Secretary also has the authority to waive such denial in such unusual cases as the Secretary finds appropriate. For more information, see the ''Medicare Program; Electronic Submission of Medicare Claims'' final rule (70 FR 71008). Our instructions for the limited number of Medicare claims submitted on paper are available at *http://www.cms.gov/manuals/downloads/clm104c25.pdf.*

Section 3 of the ASCA operates in the context of the administrative simplification provisions of HIPAA, which include, among others, the requirements for transaction standards and code sets codified in 45 CFR part 160 and part 162, subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered healthcare providers, to conduct covered electronic transactions according to the applicable transaction standards. (See the CMS program claim memoranda at *http://www.cms.gov/ElectronicBillingEDITrans/* and listed in the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

The MAC processes the claim through its software system. This software system includes pricing programming called the ''Pricer'' software. The Pricer software uses the CMG number, along with other specific claim data elements and provider-specific data, to adjust the IRF's prospective payment for interrupted stays, transfers, short stays, and deaths, and then applies the applicable adjustments to account for the IRF's wage index, percentage of low-

income patients, rural location, and outlier payments. For discharges occurring on or after October 1, 2005, the IRF PPS payment also reflects the teaching status adjustment that became effective as of FY 2006, as discussed in the FY 2006 IRF PPS final rule (70 FR 47880).

E. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their health information.

To further interoperability in post-acute care settings, CMS and Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) (*https://pacioproject.org/*) to facilitate collaboration with industry stakeholders to develop FHIR standards. These standards could support the exchange and reuse of patient assessment data derived from the minimum data set (MDS), inpatient rehabilitation facility patient assessment instrument (IRF–PAI), long term care hospital continuity assessment record and evaluation (LCDS), outcome and assessment information set (OASIS), and other sources. The PACIO Project has focused on FHIR implementation guides for functional status, cognitive status and new use cases on advance directives and speech, and language pathology. We encourage post-acute care (PAC) provider and health IT vendor participation as these efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as the authoritative resource for PAC assessment data elements and their associated mappings to health IT standards such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED). The DEL furthers CMS' goal of data standardization and interoperability. When combined with digital information systems that capture and maintain these coded elements, their standardized clinical content can reduce provider burden by supporting exchange of standardized healthcare data; supporting provider exchange of electronic health information for care coordination, person-centered care; and supporting real-time, data driven, clinical decision making. Standards in the Data Element Library (*https://del.cms.gov/DELWeb/pubHome*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2021 ISA is available at *https://www.healthit.gov/isa.*

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted on December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. The Cures Act includes a trusted exchange framework and common agreement (TEFCA) provision [4] that will enable the nationwide exchange of electronic health information across health information networks and provide an important way to enable bi-directional health information exchange in the future. For more information on current developments related to TEFCA, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement* and *https://rce.sequoiaproject.org/.*

The ONC final rule entitled, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (85 FR 25642) published in the May 1, 2020 **Federal Register** (hereinafter ''ONC Cures Act Final Rule'') implemented policies related to information blocking required under section 4003 of the 21st Century Cures Act. Information blocking is generally defined as a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information. The definition of information blocking includes a knowledge standard, which is different for health care providers than for health IT developers of certified health IT and health information networks or health information exchanges. A healthcare provider must know that the practice is unreasonable as well as likely to interfere with access, exchange, or use of electronic health information. To deter information blocking, health IT developers of certified health IT, health information networks and health information exchanges whom the HHS Inspector General determines, following an investigation, have committed information blocking, are subject to civil monetary penalties of up to $1 million per violation. Appropriate disincentives for health care providers need to be established by the Secretary through rulemaking. Stakeholders can learn more about information blocking at *https://www.healthit.gov/curesrule/final-rule-policy/information-blocking.* ONC has posted information resources including fact sheets (*https://www.healthit.gov/curesrule/resources/fact-sheets),* frequently asked questions (*https://www.healthit.gov/curesrule/resources/information-blocking-faqs*), and recorded webinars (*https://www.healthit.gov/curesrule/resources/webinars*).

We invited providers to learn more about these important developments and how they are likely to affect IRFs.

III. Summary of Provisions of the Proposed Rule

In the FY 2022 IRF PPS proposed rule, we proposed to update the IRF PPS for FY 2022 and the IRF QRP for FYs 2022 and 2023.

The proposed policy changes and updates to the IRF prospective payment rates for FY 2022 are as follows:

- Update the CMG relative weights and average length of stay values for FY 2022, in a budget neutral manner, as discussed in section IV. of the FY 2022 IRF PPS proposed rule (86 FR 19086, 19090 through 19095).
- Update the IRF PPS payment rates for FY 2022 by the market basket increase factor, based upon the most current data available, with a productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section V. of the FY 2022 IRF PPS proposed rule (86 FR 19086, 19095 through 19096).
- Update the FY 2022 IRF PPS payment rates by the FY 2022 wage index and the labor-related share in a budget-neutral manner, as discussed in section V. of the FY 2022 IRF PPS proposed rule (86 FR 19086, 19096 through 19098).
- Describe the calculation of the IRF standard payment conversion factor for FY 2022, as discussed in section V. of the FY 2022 IRF PPS proposed rule (86 FR 19086, 19098 through 19099).
- Update the outlier threshold amount for FY 2022, as discussed in section VI. of the FY 2022 IRF PPS proposed rule (86 FR 19086, 19102 through 19103).
- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2022, as discussed in

[4] ONC, *Draft 2 Trusted Exchange Framework and Common Agreement, https://www.healthit.gov/sites/default/files/page/2019-04/FINAL TEFCAQTF41719508version.pdf.*

section VI. of the FY 2022 IRF PPS proposed rule (86 FR 19086, 19103).

We also proposed policy changes and updates to the IRF QRP for FYs 2022 and 2023 as follows:

• Updates to quality measures and reporting requirements under the IRF QRP, as well as requests for information discussed in section VII. of the FY 2022 IRF PPS proposed rule (86 FR 19086, 19103 through 19116).

In a separate 2018 interim final rule with comment period (IFC), entitled ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas'' (hereinafter 2018 interim final rule), we:

• Excluded accessories furnished in connection with group 3 or higher complex rehabilitative power wheelchairs from fee schedule adjustments based on payments determined under the DMEPOS CBP (83 FR 21912 through 21925). In a 2021 notice of continuation, we announced the continuation of effectiveness of the 2018 interim final rule and the extension of the timeline for publication of the final rule (86 FR 21949).

Finally, in a separate proposed rule published on November 4, 2020, entitled ''Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS),'' we:

• Proposed to make changes to the definition of ''item'' at 42 CFR 414.402 to reflect that complex rehabilitative manual wheelchairs, certain other manual wheelchairs, and accessories furnished in connection with these wheelchairs are excluded from the DMEPOS CBP by section 106(a) of the FCAA (85 FR 70405). This is a conforming change to the regulations to implement section 106(a) of the FCAA. We are finalizing this change to 42 CFR 414.402 as part of this final rule.

IV. Analysis of and Responses to Public Comments

A. FY 2022 IRF PPS Proposed Rule

In response to the FY 2022 IRF PPS proposed rule (86 FR 19086), we received 50 timely responses from the public. We received comments from various trade associations, inpatient rehabilitation facilities, individual physicians, therapists, clinicians, health care industry organizations, and health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments that we received, and our responses.

B. 2018 Interim Final Rule

The 2018 interim final rule (83 FR 21912) included changes in fee schedule adjustments for accessories (including seating systems) and seat and back cushions furnished in connection with group 3 or higher complex rehabilitative power wheelchairs. We received 5 timely responses from wheelchair suppliers, manufacturers, and a patient advocacy organization related to fee schedule adjustments for accessories (including seating systems) and seat and back cushions furnished in connection with complex rehabilitative wheelchairs.

C. DMEPOS/HCPCS Proposed Rule

The November 2020 proposed rule (85 FR 70358) included a provision to revise the definition of ''item'' under the CBP at 42 CFR 414.402 to exclude complex rehabilitative manual wheelchairs, certain other manual wheelchairs and accessories furnished in connection with these wheelchairs from the DMEPOS CBP. We received 11 timely responses from wheelchair suppliers, manufacturers, and a national coalition of consumers and clinicians regarding excluding complex rehabilitative manual wheelchairs, certain other manual wheelchairs and related accessories furnished in connection with these wheelchairs from the CBP.

V. Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay (ALOS) Values for FY 2022

As specified in § 412.620(b)(1), we calculate a relative weight for each CMG that is proportional to the resources needed by an average inpatient rehabilitation case in that CMG. For example, cases in a CMG with a relative weight of 2, on average, will cost twice as much as cases in a CMG with a relative weight of 1. Relative weights account for the variance in cost per discharge due to the variance in resource utilization among the payment groups, and their use helps to ensure that IRF PPS payments support beneficiary access to care, as well as provider efficiency.

We proposed to update the CMG relative weights and ALOS values for FY 2022. Typically, we use the most recent available data to update the CMG relative weights and average lengths of stay. As such, section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. For FY 2022, we proposed to use the FY 2020 IRF claims and FY 2019 IRF cost report data. These data are the most current and complete data available at this time. Currently, only a small portion of the FY 2020 IRF cost report data are available for analysis, but the majority of the FY 2020 IRF claims data are available for analysis. We also proposed that if more recent data become available after the publication of the proposed rule and before the publication of the final rule, we would use such data to determine the FY 2022 CMG relative weights and ALOS values in the final rule.

We proposed to apply these data using the same methodologies that we have used to update the CMG relative weights and ALOS values each FY since we implemented an update to the methodology. The detailed CCR data from the cost reports of IRF provider units of primary acute care hospitals is used for this methodology, instead of CCR data from the associated primary care hospitals, to calculate IRFs' average costs per case, as discussed in the FY 2009 IRF PPS final rule (73 FR 46372). In calculating the CMG relative weights, we use a hospital-specific relative value method to estimate operating (routine and ancillary services) and capital costs of IRFs. The process to calculate the CMG relative weights for this final rule is as follows:

Step 1. We estimate the effects that comorbidities have on costs.

Step 2. We adjust the cost of each Medicare discharge (case) to reflect the effects found in the first step.

Step 3. We use the adjusted costs from the second step to calculate CMG relative weights, using the hospital-specific relative value method.

Step 4. We normalize the FY 2022 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the FY 2021 IRF PPS final rule (85 FR 48424).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we proposed to update the CMG relative weights for FY 2022 in such a way that total estimated aggregate payments to IRFs for FY 2022 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the standard payment amount. We note that, as we typically do, we updated our data between the FY 2022 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data reflects a more complete set of claims for FY 2020 and additional cost report data for FY 2019. To calculate the appropriate

budget neutrality factor for use in updating the FY 2022 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2022 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2022 by applying the changes to the CMG relative weights (as discussed in this final rule).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor of 1.0005 that would maintain the same total estimated aggregate payments in FY 2022 with and without the changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor from step 3 to the FY 2022 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section VI.E. of this final rule, we discuss the use of the existing methodology to calculate the standard payment conversion factor for FY 2022.

In Table 2, ''Relative Weights and Average Length of Stay Values for Case-Mix Groups,'' we present the CMGs, the comorbidity tiers, the corresponding relative weights, and the ALOS values for each CMG and tier for FY 2022. The ALOS for each CMG is used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment.

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TABLE 2: Relative Weights and Average Length of Stay Values for the Case-Mix Groups

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comor-bidity Tier	Tier 1	Tier 2	Tier 3	No Comor-bidity Tier
0101	Stroke M >=72.50	0.9741	0.8649	0.7846	0.7481	9	10	9	9
0102	Stroke M >=63.50 and M <72.50	1.2657	1.1238	1.0194	0.9720	12	12	11	11
0103	Stroke M >=50.50 and M <63.50	1.6201	1.4385	1.3049	1.2442	14	15	14	14
0104	Stroke M >=41.50 and M <50.50	2.0824	1.8489	1.6773	1.5993	18	19	18	18
0105	Stroke M <41.50 and A >=84.50	2.4437	2.1697	1.9683	1.8768	22	23	21	20
0106	Stroke M <41.50 and A <84.50	2.8656	2.5444	2.3082	2.2008	26	26	24	23
0201	Traumatic brain injury M >=73.50	1.0720	0.8842	0.8033	0.7549	11	12	9	9
0202	Traumatic brain injury M >=61.50 and M <73.50	1.3914	1.1477	1.0427	0.9799	13	13	12	11
0203	Traumatic brain injury M >=49.50 and M <61.50	1.7032	1.4048	1.2763	1.1994	14	15	14	13
0204	Traumatic brain injury M >=35.50 and M <49.50	2.0405	1.6830	1.5291	1.4370	18	18	16	16
0205	Traumatic brain injury M <35.50	2.6440	2.1808	1.9812	1.8619	28	23	20	19
0301	Non-traumatic brain injury M >=65.50	1.2322	0.9699	0.8979	0.8465	11	10	10	10
0302	Non-traumatic brain injury M >=52.50 and M <65.50	1.5841	1.2469	1.1543	1.0883	13	13	12	12
0303	Non-traumatic brain injury M >=42.50 and M <52.50	1.8983	1.4943	1.3833	1.3042	16	15	14	14
0304	Non-traumatic brain injury M <42.50 and A >=78.50	2.1743	1.7115	1.5844	1.4938	19	18	16	16
0305	Non-traumatic brain injury M <42.50 and A <78.50	2.3954	1.8856	1.7456	1.6457	21	20	17	17
0401	Traumatic spinal cord injury M >=56.50	1.4043	1.1100	1.0628	0.9638	13	12	12	11
0402	Traumatic spinal cord injury M >=47.50 and M <56.50	1.8739	1.4811	1.4182	1.2861	18	16	14	15
0403	Traumatic spinal cord injury M >=41.50 and M <47.50	2.1673	1.7130	1.6402	1.4875	19	18	17	17
0404	Traumatic spinal cord injury M <31.50 and A <61.50	3.3567	2.6531	2.5403	2.3037	36	30	25	22
0405	Traumatic spinal cord injury M >=31.50 and M <41.50	2.7525	2.1756	2.0831	1.8891	25	22	22	20
0406	Traumatic spinal cord injury M >=24.50 and M <31.50 and A >=61.50	3.6825	2.9106	2.7869	2.5273	34	30	30	26
0407	Traumatic spinal cord injury M <24.50 and A >=61.50	4.6790	3.6982	3.5410	3.2113	49	37	34	36
0501	Non-traumatic spinal cord injury M >=60.50	1.3110	0.9874	0.9279	0.8476	11	11	10	10
0502	Non-traumatic spinal cord injury M >=53.50 and M <60.50	1.6517	1.2439	1.1691	1.0678	15	13	13	12
0503	Non-traumatic spinal cord injury M >=48.50 and M <53.50	1.8945	1.4268	1.3409	1.2248	16	15	14	14
0504	Non-traumatic spinal cord injury M >=39.50 and M <48.50	2.2349	1.6831	1.5818	1.4448	20	17	17	16
0505	Non-traumatic spinal cord injury M <39.50	3.1292	2.3566	2.2148	2.0230	28	24	23	21
0601	Neurological M >=64.50	1.3639	1.0311	0.9648	0.8616	11	11	10	10
0602	Neurological M >=52.50 and M <64.50	1.6723	1.2642	1.1829	1.0563	13	13	12	12
0603	Neurological M >=43.50 and M <52.50	1.9892	1.5038	1.4071	1.2565	16	15	14	14
0604	Neurological M <43.50	2.4216	1.8306	1.7129	1.5297	20	18	17	16
0701	Fracture of lower extremity M >=61.50	1.1983	0.9559	0.9162	0.8354	11	11	10	10

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comor-bidity Tier	Tier 1	Tier 2	Tier 3	No Comor-bidity Tier
0702	Fracture of lower extremity M >=52.50 and M <61.50	1.5211	1.2134	1.1630	1.0605	13	13	13	12
0703	Fracture of lower extremity M >=41.50 and M <52.50	1.8607	1.4844	1.4227	1.2973	16	16	15	14
0704	Fracture of lower extremity M <41.50	2.2462	1.7918	1.7173	1.5660	18	18	18	17
0801	Replacement of lower-extremity joint M >=63.50	1.1454	0.8842	0.8163	0.7612	11	10	9	9
0802	Replacement of lower-extremity joint M >=57.50 and M <63.50	1.3402	1.0345	0.9551	0.8907	11	11	10	10
0803	Replacement of lower-extremity joint M >=51.50 and M <57.50	1.5058	1.1624	1.0732	1.0007	13	13	12	11
0804	Replacement of lower-extremity joint M >=42.50 and M <51.50	1.7026	1.3143	1.2134	1.1315	15	14	13	12
0805	Replacement of lower-extremity joint M <42.50	2.1052	1.6251	1.5003	1.3991	17	16	16	15
0901	Other orthopedic M >=63.50	1.2474	0.9589	0.8979	0.8143	11	11	10	9
0902	Other orthopedic M >=51.50 and M <63.50	1.5739	1.2099	1.1329	1.0274	13	13	12	12
0903	Other orthopedic M >=44.50 and M <51.50	1.8513	1.4232	1.3325	1.2085	15	15	14	13
0904	Other orthopedic M <44.5	2.1697	1.6679	1.5617	1.4164	18	17	16	15
1001	Amputation lower extremity M >=64.50	1.2459	1.0582	0.9377	0.8663	12	12	10	10
1002	Amputation lower extremity M >=55.50 and M <64.50	1.5267	1.2966	1.1490	1.0616	14	14	13	12
1003	Amputation lower extremity M >=47.50 and M <55.50	1.8234	1.5486	1.3723	1.2678	15	17	15	14
1004	Amputation lower extremity M <47.50	2.2745	1.9317	1.7118	1.5815	19	19	18	17
1101	Amputation non-lower extremity M >=58.50	1.3521	1.1226	1.0535	0.8753	13	12	11	10
1102	Amputation non-lower extremity M >=52.50 and M <58.50	1.6736	1.3896	1.3040	1.0834	14	13	14	10
1103	Amputation non-lower extremity M <52.50	1.9117	1.5873	1.4896	1.2375	16	16	15	14
1201	Osteoarthritis M >=61.50	1.4828	0.9160	0.9160	0.8199	12	10	10	10
1202	Osteoarthritis M >=49.50 and M <61.50	1.9197	1.1859	1.1859	1.0614	15	12	13	12
1203	Osteoarthritis M <49.50 and A >=74.50	2.3223	1.4346	1.4346	1.2840	17	16	16	14
1204	Osteoarthritis M <49.50 and A <74.50	2.4163	1.4927	1.4927	1.3360	17	14	16	14
1301	Rheumatoid other arthritis M >=62.50	1.2075	1.0436	0.8887	0.8225	10	12	9	10
1302	Rheumatoid other arthritis M >=51.50 and M <62.50	1.5071	1.3025	1.1092	1.0265	12	12	12	11
1303	Rheumatoid other arthritis M >=44.50 and M <51.50 and A >=64.50	1.8204	1.5733	1.3398	1.2399	14	16	14	13
1304	Rheumatoid other arthritis M <44.50 and A >=64.50	2.1663	1.8722	1.5944	1.4755	16	24	16	16
1305	Rheumatoid other arthritis M <51.50 and A <64.50	2.2382	1.9343	1.6473	1.5244	15	17	17	15
1401	Cardiac M >=68.50	1.1149	0.8988	0.8348	0.7613	10	10	9	9
1402	Cardiac M >=55.50 and M <68.50	1.4206	1.1453	1.0637	0.9701	12	12	11	11
1403	Cardiac M >=45.50 and M <55.50	1.7213	1.3877	1.2888	1.1754	15	14	13	13
1404	Cardiac M <45.50	2.0967	1.6904	1.5699	1.4318	18	17	16	15
1501	Pulmonary M >=68.50	1.2747	1.0575	0.9778	0.9192	12	11	10	9
1502	Pulmonary M >=56.50 and M <68.50	1.5560	1.2909	1.1935	1.1220	13	12	12	11

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comor-bidity Tier	Tier 1	Tier 2	Tier 3	No Comor-bidity Tier
1503	Pulmonary M >=45.50 and M <56.50	1.8145	1.5054	1.3918	1.3084	15	15	14	13
1504	Pulmonary M <45.50	2.1401	1.7755	1.6416	1.5432	20	17	16	15
1601	Pain syndrome M >=65.50	1.1148	0.8650	0.8650	0.7766	10	10	9	9
1602	Pain syndrome M >=58.50 and M <65.50	1.3201	1.0244	1.0244	0.9197	11	11	11	11
1603	Pain syndrome M >=43.50 and M <58.50	1.6241	1.2602	1.2602	1.1314	14	13	14	13
1604	Pain syndrome M <43.50	1.9087	1.4811	1.4811	1.3297	14	14	16	14
1701	Major multiple trauma without brain or spinal cord injury M >=57.50	1.4001	1.0483	0.9743	0.9013	11	12	11	11
1702	Major multiple trauma without brain or spinal cord injury M >=50.50 and M <57.50	1.7185	1.2867	1.1958	1.1062	16	14	13	12
1703	Major multiple trauma without brain or spinal cord injury M >=41.50 and M <50.50	2.0076	1.5031	1.3970	1.2923	17	16	15	14
1704	Major multiple trauma without brain or spinal cord injury M >=36.50 and M <41.50	2.3366	1.7494	1.6259	1.5040	19	19	17	16
1705	Major multiple trauma without brain or spinal cord injury M <36.50	2.5888	1.9383	1.8014	1.6664	21	20	19	18
1801	Major multiple trauma with brain or spinal cord injury M >=67.50	1.2417	0.9614	0.8857	0.8129	13	11	11	10
1802	Major multiple trauma with brain or spinal cord injury M >=55.50 and M <67.50	1.5169	1.1745	1.0820	0.9931	14	13	12	11
1803	Major multiple trauma with brain or spinal cord injury M >=45.50 and M <55.50	1.8886	1.4622	1.3471	1.2364	17	17	14	14
1804	Major multiple trauma with brain or spinal cord injury M >=40.50 and M <45.50	2.2243	1.7222	1.5865	1.4562	25	18	17	16
1805	Major multiple trauma with brain or spinal cord injury M >=30.50 and M <40.50	2.6686	2.0661	1.9034	1.7470	26	21	20	19
1806	Major multiple trauma with brain or spinal cord injury M <30.50	3.6837	2.8521	2.6275	2.4116	38	29	24	28
1901	Guillain-Barré M >=66.50	1.0699	0.8960	0.8326	0.8265	11	11	10	10
1902	Guillain-Barré M >=51.50 and M <66.50	1.5832	1.3259	1.2321	1.2230	15	14	14	14
1903	Guillain-Barré M >=38.50 and M <51.50	2.2805	1.9099	1.7748	1.7617	20	21	19	20
1904	Guillain-Barré M <38.50	3.5683	2.9884	2.7770	2.7565	39	29	29	29
2001	Miscellaneous M >=66.50	1.2066	0.9647	0.8933	0.8155	11	10	10	9
2002	Miscellaneous M >=55.50 and M <66.50	1.4890	1.1904	1.1023	1.0064	13	12	12	11
2003	Miscellaneous M >=46.50 and M <55.50	1.7562	1.4041	1.3001	1.1869	15	15	14	13
2004	Miscellaneous M <46.50 and A >=77.50	2.0661	1.6518	1.5295	1.3963	18	17	16	15
2005	Miscellaneous M <46.50 and A <77.50	2.2267	1.7802	1.6484	1.5049	19	18	16	16
2101	Burns M >=52.50	1.9303	1.3203	1.1699	1.1137	19	14	13	12
2102	Burns M <52.50	2.7884	1.9072	1.6900	1.6088	24	21	16	17
5001	Short-stay cases, length of stay is 3 days or fewer				0.1660				3

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comor-bidity Tier	Tier 1	Tier 2	Tier 3	No Comor-bidity Tier
5101	Expired, orthopedic, length of stay is 13 days or fewer				0.6930				7
5102	Expired, orthopedic, length of stay is 14 days or more				2.0491				19
5103	Expired, not orthopedic, length of stay is 15 days or fewer				0.9096				9
5104	Expired, not orthopedic, length of stay is 16 days or more				2.2526				21

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how we estimate that the application of the revisions for FY 2022 would affect particular CMG relative weight values, which would affect the overall distribution of payments within CMGs and tiers. We note that, because we implement the CMG relative weight revisions in a budget-neutral manner (as previously described), total estimated aggregate payments to IRFs for FY 2022 are not affected as a result of the CMG relative weight revisions. However, the revisions affect the distribution of payments within CMGs and tiers.

TABLE 3: Distributional Effects of the Changes to the CMG Relative Weights

Percentage Change in CMG Relative Weights	Number of Cases Affected	Percentage of Cases Affected
Increased by 15% or more	29	0.0%
Increased by between 5% and 15%	4,392	1.2%
Changed by less than 5%	367,212	97.2%
Decreased by between 5% and 15%	6,058	1.6%
Decreased by 15% or more	38	0.0%

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As shown in Table 3, 97.2 percent of all IRF cases are in CMGs and tiers that would experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the revisions for FY 2022. The changes in the ALOS values for FY 2022, compared with the FY 2021 ALOS values, are small and do not show any particular trends in IRF length of stay patterns.

The comments we received on our proposed updates to the CMG relative weights and ALOS values for FY 2022 and our responses are summarized below.

Comment: Several commenters supported the proposed updates to the CMG relative weights and ALOS values using the latest available data (the FY 2020 claims and FY 2019 cost report data). These commenters noted that applying Functional Independence Measure™ (FIM™)-based FY 2019 claims data in FY 2022 will not reflect effects of numerous changes that occurred during the COVID–19 PHE. These changes include enhanced use of personal protective equipment (PPE), increased staffing costs, COVID–19 testing for staff and patients, and other infection control protocols, to name just a few examples. However, the commenters requested more details of the analysis for determining how the COVID–19-related claims affect the relative weight and ALOS calculations.

Response: We appreciate the commenters' support for the proposed updates. The annual updates to the CMG relative weights, which include both increases and decreases to the CMG relative weights, are intended to ensure that IRF payments are aligned as closely as possible with the current costs of care. The relative weights for each of the CMGs and tiers represent the relative costliness of patients in those CMGs and tiers compared with patients in other CMGs and tiers. Using FY 2020 claims data does not result in significantly different CMG relative weight values than the relative weight values obtained using FY 2019 claims data. The relative weight budget neutrality factor would be 1.0005 using FY 2020 claims in comparison to 0.9998 using FY 2019 claims.

Additionally, with regard to providing additional analysis of the ALOS values, we found that the variation in the ALOS values between FY 2019 and FY 2020 was similar to the year-to-year fluctuations in these values that we typically see. In addition, we note that a decline in ALOS values, which the commenter expresses concern about, would actually have the effect of slightly increasing IRF PPS payments to providers, as more patients would qualify for full IRF PPS payments instead of reduced short-stay transfer payments, and the reduced short-stay transfer payments would be slightly higher (because we divide by the ALOS values in calculating the short-stay transfer per diem payment amounts). We note, also, that changes in ALOS values have no effect on IRF coverage, as these values are not used in determining coverage of IRF claims. In the IRF PPS, ALOS values are only used in determining which cases qualify for the short-stay transfer policy. Thus, we believe that the ALOS values that we are finalizing in this final rule are appropriate and will not result in any unintended consequences.

As stated in the FY 2022 IRF PPS proposed rule, the FY 2020 claims data is the most current and complete data available for updating payments. As most recently discussed in detail in the FY 2021 IRF PPS final rule (85 FR 48424), we believe that these data

accurately reflect the severity of the IRF patient population and the associated costs of caring for these patients in the IRF setting. We believe using the FY 2020 claims-based calculation reflects as accurately as possible the current costs of care in IRFs. Therefore, we believe it is appropriate to use the FY 2020 claims data to update the CMG relative weights and ALOS values for FY 2022 to ensure the case mix system is as reflective as possible of recent changes in IRF utilization and case mix. With regard to the additional request for further analysis to be provided on the use of FY 2020 claims data, CMS examined the relative weight values calculated both including and excluding cases associated with a COVID–19 ICD–10 diagnosis code. This analysis indicated that for the majority of CMGs relative weight values would change by less than 1 percent when such COVID cases were removed. In addition, we do not believe removing COVID–19 related claims from the analysis provides the best prediction of FY 2022 data because as most commenters said, we will likely still be seeing evidence of the PHE in the data for FY 2022.

Comment: Some commenters requested that CMS provide analyses of how the COVID–19 PHE would affect the IRF PPS payment rates in FY 2022. Some commenters suggested that, despite the progress being made with vaccinations and other infection control efforts, IRFs are likely to continue to treat COVID–19 survivors as well as ''Long COVID'' patients for the foreseeable future.

Response: We appreciate the commenters' suggestions and will consider providing additional analyses in future rule updates. However, we agree with most commenters, that we will be seeing evidence of the PHE in the data for FY 2022 and beyond. We believe future evaluation and impact from the PHE will generate a more robust data set for analysis giving greater insight on IRF impacts as they relate to CMG relative weights.

Comment: A few commenters stated CMS should evaluate and incorporate adjustments to the FY 2020 data for any major reductions in volumes and surgical admissions due to the PHE, which they stated resulted in a significantly different case mix from a normal year. The commenters recommended that CMS should use a blended approach (that is, blending the relative weights obtained using the FY 2019 and FY 2020 data) in determining the relative weight updates, which may mean that a larger payment increase is warranted.

Response: We appreciate the commenters' suggestions regarding changes to the methodology used to establish the CMG relative weights for the IRF PPS payments. We will continue to monitor the CMG relative weight updates to ensure that they continue to compensate IRFs appropriately. However, we disagree that a blended approach would result in the most accurate CMG relative weights, as this blended approach would not fully reflect the most recent available data (the FY 2020 IRF claims data). We believe the utilization of the FY 2020 claims data accurately reflects the severity of the IRF patient population and the associated costs of caring for these patients in the IRF setting.

Comment: One commenter expressed concerns about the underlying construction of the CMGs, specifically the commenter stated that the proposed adjustments neither account for newer coding practices nor provide adequate coverage and payment for severe patients who benefit from IRF services, thus leading to CMS relative weights and ALOS values that do not reflect current clinical practice. The commenter expressed particular concern that CMS proposed to reduce the relative weight values for patients with a stroke, traumatic brain injury, and traumatic spinal cord injury. The commenter stated that the proposed updates would decrease the relative weights for 18 of the 24 stroke CMGs, 19 of the 20 traumatic brain injury CMGs, and 16 of the 28 traumatic spinal cord injury CMGs.

Response: CMG relative weights are updated in a budget neutral manner, thus leading to increases in some relative weights and corresponding decreases in other CMG relative weights. We have carefully examined all of the decreases and increases in the CMG relative weights for FY 2022, and we believe that these changes accurately reflect our best estimates of the relative costs of caring for different types of patients in the IRF in FY 2022. As the commenter notes, the relative weights in the stroke, traumatic brain injury, and traumatic spinal cord injury conditions included both increases and decreases, and the variation for FY 2022 is similar to the typical year-to-year variation that we observe. The increases and decreases also appear to be related to severity, with the increases concentrated in the CMGs for more severe patients and the decreases concentrated in the CMGs for less severe patients. We believe that this is appropriate and reflects the most current and complete information that we have for estimating the FY 2022 relative costs of care.

Therefore, we believe that these updates more closely align IRF PPS payments with the costs of caring for different types of patients, and more closely align the average lengths of stay with the actual lengths of stay for patients in the various CMGs. As indicated previously, the magnitude of the updates for FY 2022 is similar to the changes we see in a typical year.

Regarding the updates to ''new coding practices'', we are not certain what the commenter means, but if, as we suspect, they may be referring to the changes in the CMGs and the data used to assign those CMGs, then our analysis indicates the FY 2020 IRF claims and the FY 2019 IRF cost report data provides the best available data for setting the CMS relative weights for FY 2022.

After consideration of the comments we received, we are finalizing our proposal to update the CMG relative weights and ALOS values for FY 2022, as shown in Table 2 of this final rule. These updates are effective for FY 2022, that is, for discharges occurring on or after October 1, 2021 and on or before September 30, 2022.

VI. FY 2022 IRF PPS Payment Update

A. Background

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services for which payment is made under the IRF PPS. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF prospective payment rates for each FY. Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Thus, in the FY 2022 IRF PPS proposed rule, we proposed to update the IRF PPS payments for FY 2022 by a market basket increase factor as required by section 1886(j)(3)(C) of the Act based upon the most current data available, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

We have utilized various market baskets through the years in the IRF PPS. For a discussion of these market baskets, we refer readers to the FY 2016 IRF PPS final rule (80 FR 47046).

In FY 2016, we finalized the use of a 2012-based IRF market basket, using Medicare cost report (MCR) data for both freestanding and hospital-based IRFs (80 FR 47049 through 47068). Beginning with FY 2020, we finalized a rebased and revised IRF market basket to reflect a 2016 base year. The FY 2020

IRF PPS final rule (84 FR 39071 through 39086) contains a complete discussion of the development of the 2016-based IRF market basket.

B. FY 2022 Market Basket Update and Productivity Adjustment

For FY 2022 (that is, beginning October 1, 2021 and ending September 30, 2022), we proposed to update the IRF PPS payments by a market basket increase factor as required by section 1886(j)(3)(C) of the Act, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act. For FY 2022, we proposed to use the same methodology described in the FY 2021 IRF PPS final rule (85 FR 48432 through 48433), with one proposed modification to the 2016-based IRF market basket.

For the price proxy for the For-profit Interest cost category of the 2016-based IRF market basket, we proposed to use the iBoxx AAA Corporate Bond Yield index instead of the Moody's AAA Corporate Bond Yield index. Effective for December 2020, the Moody's AAA Corporate Bond series is no longer available for use under license to IHS Global Inc. (IGI), the nationally-recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and multi-factor productivity (MFP). Since IGI is no longer licensed to use and publish the Moody's series, IGI was required to discontinue the publication of the associated historical data and forecasts of this series. Therefore, IGI constructed a bond yield index (iBoxx) that closely replicates the Moody's corporate bond yield indices currently used in the market baskets.

In the FY 2022 IRF PPS proposed rule, we stated that because the iBoxx AAA Corporate Bond Yield index captures the same technical concept as the current corporate bond proxy and tracks similarly to the current measure that is no longer available, we believed that the iBoxx AAA Corporate Bond Yield index is technically appropriate to use in the 2016-based IRF market basket.

Consistent with historical practice, we proposed to estimate the market basket update for the IRF PPS for FY 2022 based on IGI's forecast using more recent available data. Based on IGI's fourth quarter 2020 forecast with historical data through the third quarter of 2020, the proposed 2016-based IRF market basket increase factor for FY 2022 was projected to be 2.4 percent. We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket update or MFP), we would use such data, if appropriate, to determine the FY 2022 market basket update in this final rule.

According to section 1886(j)(3)(C)(i) of the Act, the Secretary shall establish an increase factor based on an appropriate percentage increase in a market basket of goods and services. Section 1886(j)(3)(C)(ii) of the Act then requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, 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 sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''productivity adjustment''). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* for the BLS historical published MFP data. A complete description of the MFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Dataand-Systems/Statistics-Trends-andReports/MedicareProgramRatesStats/MarketBasketResearch.html.* We note that effective with FY 2022 and forward, CMS is changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We note that this is not a change in policy as the methodology for deriving the adjustment relies on the same underlying data and methodology. This change in terminology results in a title more consistent with the statutory language described in section 1886(j)(3)(C)(ii) of the Act.

Using IGI's fourth quarter 2020 forecast, the 10-year moving average growth of MFP for FY 2022 was projected to be 0.2 percent. Thus, in accordance with section 1886(j)(3)(C) of the Act, we proposed to base the FY 2022 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on IGI's fourth quarter 2020 forecast of the 2016-based IRF market basket. We proposed to then reduce this percentage increase by the estimated productivity adjustment for FY 2022 of 0.2 percentage point (the 10-year moving average growth of MFP for the period ending FY 2022 based on IGI's fourth quarter 2020 forecast). Therefore, the proposed FY 2022 IRF update was equal to 2.2 percent (2.4 percent market basket update reduced by the 0.2 percentage point productivity adjustment).

Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket and/or MFP), we would use such data, if appropriate, to determine the FY 2022 market basket update and productivity adjustment in this final rule.

Based on the more recent data available for this FY 2022 IRF final rule (that is, IGI's second quarter 2021 forecast of the 2016-based IRF market basket with historical data through the first quarter of 2021), we estimate that the IRF FY 2022 market basket update is 2.6 percent. Based on the more recent data available from IGI's second quarter 2021 forecast, the current estimate of the productivity adjustment for FY 2022 is 0.7 percentage point. Therefore, the current estimate of the FY 2022 IRF increase factor is equal to 1.9 percent (2.6 percent market basket update reduced by 0.7 percentage point productivity adjustment).

For FY 2022, the Medicare Payment Advisory Commission (MedPAC) recommends that we reduce IRF PPS payment rates by 5 percent. As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary proposed to update the IRF PPS payment rates for FY 2022 by a productivity-adjusted IRF market basket increase factor of 2.2 percent. Based on more recent data, the current estimate of the productivity-adjusted IRF market basket increase factor is 1.9 percent. Section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2022.

We invited public comment on our proposals for the FY 2022 market basket update and productivity adjustment. The following is a summary of the public comments received on the proposed FY 2022 market basket update and productivity adjustment and our responses:

Comment: One commenter supported the change to the iBoxx AAA Corporate Bond Yield index for use in the IRF market basket price proxy for the For-profit interest cost category in lieu of the Moody's AAA Corporate Bond Yield Index that is no longer available.

Response: We appreciate the commenter's support of the use of the iBoxx AAA Corporate Bond Yield index as the replacement price proxy for the for-profit interest cost category in the 2016-based IRF market basket.

Comment: A few commenters noted their appreciation for the proposed increase in IRF payments as a result of the productivity-adjusted market basket update. Several commenters supported CMS continuing to update the market basket and productivity factor using the latest available data in the IRF PPS final rule.

Response: We appreciate the commenters' support for the use of the productivity-adjusted market basket to annually update IRF PPS payments. As proposed, we are using the latest available data to determine the FY 2022 IRF market basket update and productivity adjustment.

Comment: Several commenters expressed concern that the impact of the PHE due to COVID–19 is not factored into the payment rate update. One commenter stated that the PHE has required and continues to require IRFs to increase their labor costs through increased use of contract labor; incurrence of substantial additional paid time off for nurses and therapists who have contracted COVID–19 or been quarantined due to potential exposure to this disease; increased operating costs related to purchases of additional PPE; increases in purchases of other supply costs; and increased costs of cleaning supplies, among other cost increases. The commenters also stated that while many of these new or increased costs will likely extend into FY 2022, the current market basket update factors do not have these costs embedded into the underlying payment rate update. Commenters encouraged CMS to consider these factors and embed an additional update to account for this added cost to IRFs. Another commenter stated that while they appreciate the modest increase to the IRF payment rate, they believe it is insufficient to offset the negative financial impact of cost inflation and the COVID–19 pandemic and encouraged CMS to consider additional funding opportunities in the final rule. One commenter requested that CMS measure the impacts of COVID–19 and include them in the analysis for the final IRF rule.

Response: For this final rule, we have incorporated more recent historical data and forecasts provided by IGI to capture the price and wage pressures facing IRFs. By incorporating the more recent estimates available of the market basket update and productivity adjustment, we believe these data reflect the best available projection of input price inflation faced by IRFs for FY 2022, adjusted for economy-wide productivity, which is required by statute.

The current IRF market basket cost weights are based on Medicare cost report data from 2016. Typically, a market basket is rebased every 4 to 5 years. However, we continually monitor the cost weights in the market baskets to ensure they are reflecting the mix of inputs used in providing services. We do not yet have cost report data available to determine the impact of COVID–19 on IRF cost structures. When complete Medicare cost report data covering the full impact of the PHE become available, we plan to review this information for future rulemaking. Any future rebasing or revising of the IRF market basket will be proposed and subject to public comments in future rulemaking.

While the update factor for IRFs for FY 2022 use data that reflect the best available projection of input price inflation faced by IRFs, we acknowledge the commenters' concern that the rate update may not reflect certain additional costs incurred during the COVID–19 PHE. However, we note that Medicare providers, may be eligible for payments from the Provider Relief Fund (as authorized by Division B, Title VIII of the CARES Act, Division B, Title I of the Paycheck Protection Program and Health Care Enhancement Act (Pub. L. 116–139, enacted April 24, 2020), and Division M Title III of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, enacted December 27, 2020) or the American Rescue Plan Act (ARPA) Rural Distribution (as authorized by section 9911 of the American Rescue Plan Act of 2021) (Pub. L. 117–2, enacted March 11, 2021) to cover health-care related expenses and lost revenues attributed to COVID–19. The total appropriation for the Provider Relief Fund is $178 billion. These payments are intended to help healthcare providers respond to the productivity losses and extra expenses caused by the PHE.

IRFs are eligible to apply for reimbursement for providing COVID–19 testing, treatment, or vaccine administration to uninsured people. These payments are available from the COVID–19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment and Vaccine Administration for the Uninsured Program (additional information about the Uninsured Program can be found at *https://www.hrsa.gov/coviduninsuredclaim*). IRFs are also eligible to apply to the HRSA COVID–19 Coverage Assistance Fund (CAF) for reimbursement for administering COVID–19 vaccines to underinsured individuals, defined as those whose health plan either does not cover vaccines, or covers them with patient cost-sharing (additional information about the CAF can be found at *https://www.hrsa.gov/covid19-coverage-assistance*.)

In accordance with statutory requirements, the Provider Relief Fund and ARPA Rural payments may not be used to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse. Likewise, we do not believe that it is appropriate to account for PHE-related costs in our IRF rate setting to the extent that such costs were actually reimbursed by the Provider Relief Fund or may be reimbursed by the ARPA Rural Distribution program.

Comment: One commenter expressed concerns about the continued application of the productivity adjustment to IRFs. The commenter also stated that while it understands that CMS is bound by statute to reduce the market basket update by a productivity adjustment factor in accordance with the ACA, it remains concerned that IRFs will not have the ability to generate additional productivity gains at a pace matching the productivity of the economy at large on an ongoing, consistent basis as contemplated by the ACA. The commenter further stated that recent developments related to the PHE due to COVID–19 have resulted in further productivity challenges for IRFs and a loss of productivity efficiencies. The commenter stated that hospitals have been impacted by the additional costs and administrative processes associated with the PHE and various guidance and requirements issued by federal, state, and local health authorities arising as a result of it, such as—but by no means limited to—screening or testing of all employees, visitors, and vendors coming through the doors for COVID–19; revamping housekeeping processes and schedules; increased provision of in-room therapy; reorienting the patients and employees to new food/meal service processes, which includes in-room only meals for patients; the clinical inefficiencies of donning and doffing of PPE; the quarantining of employees with known or possible detection of COVID–19; purchasing of in-house COVID–19 testing devices; and the tracking and reporting of COVID–19 cases, tests, and vaccines administered, among other reporting requirements. The commenter

stated that it is not clear when or whether these and other process changes will end. The commenter further stated that the PHE has caused disruption to staffing efficiencies, required staff to quarantine, and required them to alter their treatment patterns to care for COVID–19 positive patients. They noted that the PHE has underscored the concern that year-over-year productivity gains are unattainable and do not track with actual IRF operational experience. The commenter requested CMS monitor the impact that the productivity adjustments will have on the rehabilitation hospital sector and provide feedback to Congress as appropriate, and reduce the productivity adjustment.

Response: As the commenter acknowledged, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment to the IRF PPS market basket increase factor. In response to the commenter's request to reduce the productivity adjustment, we note that we are required by statute to use an economy-wide productivity measure to derive this productivity adjustment. The current projection of the productivity adjustment for FY 2022 is provided by an independent contractor, IGI, and reflects their recent expectations regarding the 10-year moving average growth in private nonfarm business MFP for the period ending FY 2022. As requested by the commenter, we will continue to monitor the impact of the payment updates on IRF Medicare payment adequacy as well as beneficiary access to care.

We also note that the Provider Relief Fund and ARPA Rural Distribution payments discussed above are intended to help providers, including IRFs, respond to additional expenses and productivity losses caused by the PHE. We do not believe that the COVID–19 expenses that the commenter discusses in any way alter CMS' responsibility to estimate and apply a multifactor productivity adjustment to the IRF increase factor, as required by section 1886(j)(3)(C)(ii)(I) of the Act.

As stated in the FY 2020 IRF PPS final rule (84 FR 39087) and the FY 2021 IRF PPS final rule (85 FR 48443), we would be interested in better understanding IRF-specific productivity, including any insights into available data at the level required to estimate IRF-specific multi-factor productivity that would allow this analysis.

Comment: Several commenters recommended that CMS continue to examine productivity factors for health care providers and hospitals and provide findings to Congress in order to implement a more appropriate, healthcare specific productivity adjustment. One commenter recommended that CMS recommend to Congress a more specific productivity adjustment that would properly reflect the nature of healthcare services, and in particular, hospital services.

Response: We have estimated hospital-sector multi-factor productivity and regularly publish updated findings at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf.* As more recent data become available regarding hospital-sector productivity, we plan to continue updating these estimates and reporting this information on our website. In addition, we note that MedPAC annually monitors various factors for Medicare providers in terms of profitability and beneficiary access to care and reports the findings to Congress on an annual basis. In chapter 9 of its March 2021 report to Congress, MedPAC has recommended that payments to IRF facilities be reduced because the Commission determined that Medicare's current payment rates for IRFs appear to be more than adequate. As noted previously, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment based on the economy-wide productivity measure to the IRF PPS market basket increase factor.

Comment: MedPAC commented that while it understands that CMS is required to implement the statutory payment update; it noted that MedPAC determined that Medicare's current payment rates for IRFs appear to be more than adequate and recommended that the Congress reduce the IRF payment rate by 5 percent for FY 2022.

Response: We are required to update IRF PPS payments by the market basket update adjusted for productivity, as directed by section 1886(j)(3)(C) of the Act. Any change to the productivity adjusted-market basket update would need to be made through legislation.

Comment: One commenter noted that FY 2021 was the second year in a row where MedPAC has recommended a decrease in payments and CMS did not accept the recommendation. The commenter stated that MedPAC's recommendation was flawed for several reasons. The commenter disagreed that the metrics utilizing case-mix groups (CMG) payments are site neutral since one for-profit company alone controls one third of the U.S. Medicare IRF market, resulting in statistical bias. The commenter also stated that the proposed rule, with regards to the proposed increase for payments to IRF providers, should be withdrawn and reconsidered.

Response: We appreciate the commenter's concern regarding the payment increase for IRFs; however, we do not have the statutory authority to implement MedPAC's recommendation. As discussed, and in accordance with sections 1886(j)(3)(C), the Secretary is updating IRF PPS payment rates for FY 2022 by an adjusted market basket increase factor of 1.9 percent, as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2022. The CMGs utilized under the IRF PPS were implemented in accordance with statute and incorporate case-level and facility-level adjustments to best align IRF prospective payments with the expected costs of treating patients in the IRF setting.

After consideration of the comments we received, we are finalizing a FY 2022 IRF update equal to 1.9 percent based on the most recent data available.

C. Labor-Related Share for FY 2022

Section 1886(j)(6) of the Act specifies that the Secretary is to adjust the proportion (as estimated by the Secretary from time to time) of IRFs' costs that are attributable to wages and wage-related costs, of the prospective payment rates computed under section 1886(j)(3) of the Act, for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We proposed to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2016-based IRF market basket, we proposed to calculate the labor-related share for FY 2022 as the sum of the FY 2022 relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-related Services, and a portion of the Capital-Related relative importance from the 2016-based IRF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the 2016-based IRF labor-

related share, see the FY 2020 IRF PPS final rule (84 FR 39087 through 39089).

The relative importance reflects the different rates of price change for these cost categories between the base year (2016) and FY 2022. Based on IGI's fourth quarter 2020 forecast of the 2016-based IRF market basket, the sum of the FY 2022 relative importance for Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services was 69.0 percent. We proposed that the portion of Capital-Related costs that are influenced by the local labor market is 46 percent. Since the relative importance for Capital-Related costs was 8.4 percent of the 2016-based IRF market basket for FY 2022, we proposed to take 46 percent of 8.4 percent to determine the labor-related share of Capital-Related costs for FY 2022 of 3.9 percent. Therefore, we proposed a total labor-related share for FY 2022 of 72.9 percent (the sum of 69.0 percent for the labor-related share of operating costs and 3.9 percent for the labor-related share of Capital-Related costs). We proposed that if more recent data became available after publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the labor-related share), we would use such data, if appropriate, to determine the FY 2022 IRF labor-related share in the final rule.

Based on IGI's second quarter 2021 forecast of the 2016-based IRF market basket, the sum of the FY 2022 relative importance for Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services is 69.0 percent. Since the relative importance for Capital-Related costs is 8.4 percent of the 2016-based IRF market basket for FY 2022, we take 46 percent of 8.4 percent to determine the labor-related share of Capital-Related costs for FY 2022 of 3.9 percent. Therefore, the current estimate of the total labor-related share for FY 2022 is equal to 72.9 percent (the sum of 69.0 percent for the labor-related share of operating costs and 3.9 percent for the labor-related share of Capital-Related costs).

Table 4 shows the current estimate of the FY 2022 labor-related share and the FY 2021 final labor-related share using the 2016-based IRF market basket relative importance.

TABLE 4: FY 2022 IRF Labor-Related Share and FY 2021 IRF Labor-Related Share

	FY 2022 Labor-Related Share [1]	FY 2021 Final Labor Related Share [2]
Wages and Salaries	48.3	48.6
Employee Benefits	11.4	11.4
Professional Fees: Labor-Related [3]	5.0	5.0
Administrative and Facilities Support Services	0.8	0.7
Installation, Maintenance, and Repair Services	1.6	1.6
All Other: Labor-Related Services	1.9	1.8
Subtotal	**69.0**	**69.1**
Labor-related portion of Capital-Related (46%)	3.9	3.9
Total Labor-Related Share	**72.9**	**73.0**

[1] Based on the 2016-based IRF market basket relative importance, IGI 2nd quarter 2021 forecast.

[2] Based on the 2016-based IRF market basket relative importance as published in the **Federal Register** (85 FR 48434).

[3] Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management consulting, and home office contract labor costs.

We invited public comment on the proposed labor-related share for FY 2022.

We did not receive any comments on the proposed revisions to the labor related share for FY 2022 and, therefore, we are finalizing the use of the sum of the FY 2022 relative importance for the labor-related cost categories based on the most recent forecast (IGI's second quarter 2021 forecast) of the 2016-based IRF market basket labor-related share cost weights, as proposed.

D. Wage Adjustment for FY 2022

1. Background

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion of rehabilitation facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the IRF PPS wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustment or updates made under section 1886(j)(6) of the Act for a FY are made in a budget-neutral manner.

For FY 2022, we proposed to maintain the policies and methodologies described in the FY 2021 IRF PPS final rule (85 FR 48435) related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we proposed to use the core based statistical areas (CBSAs) labor market area definitions and the FY 2022 pre-reclassification and pre-floor hospital wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2022 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018 (that is, FY 2018 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the IRF PPS wage index. We proposed to continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the

calculation for the FY 2022 IRF PPS wage index.

We invited public comment on our proposals regarding the Wage Adjustment for FY 2022.

The following is a summary of the public comments received on the proposed revisions to Wage Adjustment for FY 2022 and our responses:

Comment: Some commenters who were supportive of using the concurrent year's IPPS wage data requested that CMS adopt other IPPS wage index methodologies for the IRF PPS, including geographic reclassification and the imposition of a rural floor.

Response: We appreciate the commenters' support for the continued use of the concurrent year's IPPS wage data. However, we note that the IRF PPS does not account for geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act, and does not apply the ''rural floor'' under section 4410 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997). Furthermore, as we do not have an IRF-specific wage index, we are unable to determine the degree, if any, to which a geographic reclassification adjustment or a rural floor policy under the IRF PPS would be appropriate. The rationale for our current wage index policies was most recently published in the FY 2021 IRF PPS final rule (85 FR 48435 through 48436) and fully described in the FY 2006 IRF PPS final rule (70 FR 47880, 47926 through 47928).

Comment: Several commenters requested that we apply a 5 percent wage index cap to ensure that wage index values do not change by more than 5 percent from year-to-year to protect IRFs from larger payment volatility.

Response: We note that certain changes to wage index policy may significantly affect Medicare payments. These changes may arise from revisions to the OMB delineations of statistical areas resulting from the decennial census data, periodic updates to the OMB delineations in the years between the decennial censuses, or other wage index policy changes. While we consider how best to address these potential scenarios in a consistent and thoughtful manner, we reiterate that our policy principles with regard to the wage index include generally using the most current data and information available and providing that data and information, as well as any approaches to addressing any significant effects on Medicare payments resulting from these potential scenarios, in notice and comment rulemaking. We also note that any hospital wage data used to derive the IRF PPS wage index would be available from the CMS IPPS wage index website for each respective FY, which can be accessed from *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.*

Comment: Several commenters requested that we provide additional wage index data that relate to changes for low-wage index areas that were finalized in the FY 2021 IPPS final rule.

Response: Data pertaining to the FY 2021 IPPS final rule are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.* We do not have any additional data on this for the IRF PPS.

After considering the comments received, for the reasons discussed above and in the FY 2022 IRF PPS proposed rule (86 FR 19097), we are finalizing our proposal to continue to use the updated hospital inpatient wage data, exclusive of the occupational mix and floor adjustments, to develop the IRF PPS wage index.

2. Core-Based Statistical Areas (CBSAs) for the FY 2022 IRF Wage Index

a. Background

The wage index used for the IRF PPS is calculated using the pre-reclassification and pre-floor inpatient PPS (IPPS) wage index data and is assigned to the IRF on the basis of the labor market area in which the IRF is geographically located. IRF labor market areas are delineated based on the CBSAs established by the OMB. The CBSA delineations (which were implemented for the IRF PPS beginning with FY 2016) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2016 IRF PPS final rule (80 FR 47068 through 47076) for a full discussion of our implementation of the OMB labor market area delineations beginning with the FY 2016 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. Additionally, OMB occasionally issues updates and revisions to the statistical areas in between decennial censuses to reflect the recognition of new areas or the addition of counties to existing areas. In some instances, these updates merge formerly separate areas, transfer components of an area from one area to another, or drop components from an area. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides minor 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.

In the FY 2018 IRF PPS final rule (82 FR 36250 through 36251), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2017, beginning with the FY 2018 IRF wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2018 IRF PPS final rule. In the FY 2019 IRF PPS final rule (83 FR 38527), we continued to use the OMB delineations that were adopted beginning with FY 2016 to calculate the area wage indexes, with updates set forth in OMB Bulletin No. 15–01 that we adopted beginning with the FY 2018 wage index.

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 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 the FY 2020 IRF PPS final rule (84 FR 39090 through 39091), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2019, beginning with the FY 2020 IRF wage index.

On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017 OMB Bulletin No. 17–01, and on September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the

delineations of these statistical areas. A copy of this bulletin may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.*

To this end, as discussed in the FY 2021 IRF PPS proposed (85 FR 22075 through 22079) and final (85 FR 48434 through 48440) rules, we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) beginning October 1, 2020, including a 1-year transition for FY 2021 under which we applied a 5 percent cap on any decrease in an IRF's wage index compared to its wage index for the prior fiscal year (FY 2020). The updated OMB delineations more accurately reflect the contemporary urban and rural nature of areas across the country, and the use of such delineations allows us to determine more accurately the appropriate wage index and rate tables to apply under the IRF PPS.

OMB issued further revised CBSA delineations in OMB Bulletin No. 20–01, on March 6, 2020 (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). However, we have determined that the changes in OMB Bulletin No. 20–01 do not impact the CBSA-based labor market area delineations adopted in FY 2021. Therefore, CMS did not propose to adopt the revised OMB delineations identified in OMB Bulletin No. 20–01 for FY 2022.

4. Wage Adjustment

To calculate the wage-adjusted facility payment for the payment rates set forth in this final rule, we multiply the unadjusted Federal payment rate for IRFs by the FY 2022 labor-related share based on the 2016-based IRF market basket relative importance (72.9 percent) to determine the labor-related portion of the standard payment amount. A full discussion of the calculation of the labor-related share is located in section VI.C. of this final rule. We then multiply the labor-related portion by the applicable IRF wage index. The wage index tables are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html.*

Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a budget-neutral manner. We proposed to calculate a budget-neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at § 412.624(e)(1), as described in the steps below. We proposed to use the listed steps to ensure that the FY 2022 IRF standard payment conversion factor reflects the proposed update to the wage indexes (based on the FY 2018 hospital cost report data) and the proposed update to the labor-related share, in a budget-neutral manner:

Step 1. Calculate the total amount of estimated IRF PPS payments using the labor-related share and the wage indexes from FY 2021 (as published in the FY 2021 IRF PPS final rule (85 FR 48424)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the FY 2022 wage index values (based on updated hospital wage data) and the FY 2022 labor-related share of 72.9 percent.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2022 budget-neutral wage adjustment factor of 1.0032.

Step 4. Apply the budget neutrality factor from step 3 to the FY 2022 IRF PPS standard payment amount after the application of the increase factor to determine the FY 2022 standard payment conversion factor.

We discuss the calculation of the standard payment conversion factor for FY 2022 in section VI.E. of this final rule.

We did not receive any comments on the proposed revisions to the IRF wage adjustment for FY 2022, and therefore, we are finalizing the revisions as proposed.

E. Description of the IRF Standard Payment Conversion Factor and Payment Rates for FY 2022

To calculate the standard payment conversion factor for FY 2022, as illustrated in Table 5, we begin by applying the increase factor for FY 2022, as adjusted in accordance with sections 1886(j)(3)(C) of the Act, to the standard payment conversion factor for FY 2021 ($16,856). Applying the 1.9 percent increase factor for FY 2022 to the standard payment conversion factor for FY 2021 of $16,856 yields a standard payment amount of $17,176. Then, we apply the budget neutrality factor for the FY 2022 wage index, and labor-related share of 1.0032, which results in a standard payment amount of $17,231. We next apply the budget neutrality factor for the CMG relative weights of 1.0005, which results in the standard payment conversion factor of $17,240 for FY 2022.

We invited public comment on the proposed FY 2022 standard payment conversion factor.

We did not receive any comments on the proposed revisions to the FY 2022 standard payment conversion factor, and therefore, we are finalizing the revisions as proposed.

TABLE 5: Calculations to Determine the FY 2022 Standard Payment Conversion Factor

Explanation for Adjustment	Calculations	
Standard Payment Conversion Factor for FY 2021		$16,856
Market Basket Increase Factor for FY 2022 (2.6 %), reduced by 0.7 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act	x	1.019
Budget Neutrality Factor for the Updates to the Wage Index and Labor-Related Share	x	1.0032
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	x	1.0005
FY 2022 Standard Payment Conversion Factor	=	$17,240

After the application of the CMG relative weights described in section V. of the proposed rule to the proposed FY 2022 standard payment conversion factor ($17,240), the resulting unadjusted IRF prospective payment rates for FY 2022 are shown in Table 6.

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TABLE 6: FY 2022 Payment Rates

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0101	$16,793.48	$14,910.88	$13,526.50	$12,897.24
0102	$21,820.67	$19,374.31	$17,574.46	$16,757.28
0103	$27,930.52	$24,799.74	$22,496.48	$21,450.01
0104	$35,900.58	$31,875.04	$28,916.65	$27,571.93
0105	$42,129.39	$37,405.63	$33,933.49	$32,356.03
0106	$49,402.94	$43,865.46	$39,793.37	$37,941.79
0201	$18,481.28	$15,243.61	$13,848.89	$13,014.48
0202	$23,987.74	$19,786.35	$17,976.15	$16,893.48
0203	$29,363.17	$24,218.75	$22,003.41	$20,677.66
0204	$35,178.22	$29,014.92	$26,361.68	$24,773.88
0205	$45,582.56	$37,596.99	$34,155.89	$32,099.16
0301	$21,243.13	$16,721.08	$15,479.80	$14,593.66
0302	$27,309.88	$21,496.56	$19,900.13	$18,762.29
0303	$32,726.69	$25,761.73	$23,848.09	$22,484.41
0304	$37,484.93	$29,506.26	$27,315.06	$25,753.11
0305	$41,296.70	$32,507.74	$30,094.14	$28,371.87
0401	$24,210.13	$19,136.40	$18,322.67	$16,615.91
0402	$32,306.04	$25,534.16	$24,449.77	$22,172.36
0403	$37,364.25	$29,532.12	$28,277.05	$25,644.50
0404	$57,869.51	$45,739.44	$43,794.77	$39,715.79
0405	$47,453.10	$37,507.34	$35,912.64	$32,568.08
0406	$63,486.30	$50,178.74	$48,046.16	$43,570.65
0407	$80,665.96	$63,756.97	$61,046.84	$55,362.81
0501	$22,601.64	$17,022.78	$15,997.00	$14,612.62
0502	$28,475.31	$21,444.84	$20,155.28	$18,408.87
0503	$32,661.18	$24,598.03	$23,117.12	$21,115.55
0504	$38,529.68	$29,016.64	$27,270.23	$24,908.35
0505	$53,947.41	$40,627.78	$38,183.15	$34,876.52
0601	$23,513.64	$17,776.16	$16,633.15	$14,853.98
0602	$28,830.45	$21,794.81	$20,393.20	$18,210.61
0603	$34,293.81	$25,925.51	$24,258.40	$21,662.06
0604	$41,748.38	$31,559.54	$29,530.40	$26,372.03
0701	$20,658.69	$16,479.72	$15,795.29	$14,402.30
0702	$26,223.76	$20,919.02	$20,050.12	$18,283.02
0703	$32,078.47	$25,591.06	$24,527.35	$22,365.45
0704	$38,724.49	$30,890.63	$29,606.25	$26,997.84
0801	$19,746.70	$15,243.61	$14,073.01	$13,123.09
0802	$23,105.05	$17,834.78	$16,465.92	$15,355.67
0803	$25,959.99	$20,039.78	$18,501.97	$17,252.07
0804	$29,352.82	$22,658.53	$20,919.02	$19,507.06
0805	$36,293.65	$28,016.72	$25,865.17	$24,120.48
0901	$21,505.18	$16,531.44	$15,479.80	$14,038.53
0902	$27,134.04	$20,858.68	$19,531.20	$17,712.38
0903	$31,916.41	$24,535.97	$22,972.30	$20,834.54
0904	$37,405.63	$28,754.60	$26,923.71	$24,418.74
1001	$21,479.32	$18,243.37	$16,165.95	$14,935.01
1002	$26,320.31	$22,353.38	$19,808.76	$18,301.98
1003	$31,435.42	$26,697.86	$23,658.45	$21,856.87
1004	$39,212.38	$33,302.51	$29,511.43	$27,265.06
1101	$23,310.20	$19,353.62	$18,162.34	$15,090.17
1102	$28,852.86	$23,956.70	$22,480.96	$18,677.82
1103	$32,957.71	$27,365.05	$25,680.70	$21,334.50
1201	$25,563.47	$15,791.84	$15,791.84	$14,135.08
1202	$33,095.63	$20,444.92	$20,444.92	$18,298.54
1203	$40,036.45	$24,732.50	$24,732.50	$22,136.16
1204	$41,657.01	$25,734.15	$25,734.15	$23,032.64

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
1301	$20,817.30	$17,991.66	$15,321.19	$14,179.90
1302	$25,982.40	$22,455.10	$19,122.61	$17,696.86
1303	$31,383.70	$27,123.69	$23,098.15	$21,375.88
1304	$37,347.01	$32,276.73	$27,487.46	$25,437.62
1305	$38,586.57	$33,347.33	$28,399.45	$26,280.66
1401	$19,220.88	$15,495.31	$14,391.95	$13,124.81
1402	$24,491.14	$19,744.97	$18,338.19	$16,724.52
1403	$29,675.21	$23,923.95	$22,218.91	$20,263.90
1404	$36,147.11	$29,142.50	$27,065.08	$24,684.23
1501	$21,975.83	$18,231.30	$16,857.27	$15,847.01
1502	$26,825.44	$22,255.12	$20,575.94	$19,343.28
1503	$31,281.98	$25,953.10	$23,994.63	$22,556.82
1504	$36,895.32	$30,609.62	$28,301.18	$26,604.77
1601	$19,219.15	$14,912.60	$14,912.60	$13,388.58
1602	$22,758.52	$17,660.66	$17,660.66	$15,855.63
1603	$27,999.48	$21,725.85	$21,725.85	$19,505.34
1604	$32,905.99	$25,534.16	$25,534.16	$22,924.03
1701	$24,137.72	$18,072.69	$16,796.93	$15,538.41
1702	$29,626.94	$22,182.71	$20,615.59	$19,070.89
1703	$34,611.02	$25,913.44	$24,084.28	$22,279.25
1704	$40,282.98	$30,159.66	$28,030.52	$25,928.96
1705	$44,630.91	$33,416.29	$31,056.14	$28,728.74
1801	$21,406.91	$16,574.54	$15,269.47	$14,014.40
1802	$26,151.36	$20,248.38	$18,653.68	$17,121.04
1803	$32,559.46	$25,208.33	$23,224.00	$21,315.54
1804	$38,346.93	$29,690.73	$27,351.26	$25,104.89
1805	$46,006.66	$35,619.56	$32,814.62	$30,118.28
1806	$63,506.99	$49,170.20	$45,298.10	$41,575.98
1901	$18,445.08	$15,447.04	$14,354.02	$14,248.86
1902	$27,294.37	$22,858.52	$21,241.40	$21,084.52
1903	$39,315.82	$32,926.68	$30,597.55	$30,371.71
1904	$61,517.49	$51,520.02	$47,875.48	$47,522.06
2001	$20,801.78	$16,631.43	$15,400.49	$14,059.22
2002	$25,670.36	$20,522.50	$19,003.65	$17,350.34
2003	$30,276.89	$24,206.68	$22,413.72	$20,462.16
2004	$35,619.56	$28,477.03	$26,368.58	$24,072.21
2005	$38,388.31	$30,690.65	$28,418.42	$25,944.48
2101	$33,278.37	$22,761.97	$20,169.08	$19,200.19
2102	$48,072.02	$32,880.13	$29,135.60	$27,735.71
5001	$ -	$ -	$ -	$2,861.84
5101	$ -	$ -	$ -	$11,947.32
5102	$ -	$ -	$ -	$35,326.48
5103	$ -	$ -	$ -	$15,681.50
5104	$ -	$ -	$ -	$38,834.82

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F. Example of the Methodology for Adjusting the Prospective Payment Rates

Table 7 illustrates the methodology for adjusting the prospective payments (as described in section VI. of this final rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0104 (without comorbidities). The unadjusted prospective payment rate for CMG 0104 (without comorbidities) appears in Table 7.

Example: One beneficiary is in Facility A, an IRF located in rural Spencer County, Indiana, and another beneficiary is in Facility B, an IRF located in urban Harrison County, Indiana. Facility A, a rural non-teaching hospital has a Disproportionate Share Hospital (DSH) percentage of 5 percent (which would result in a LIP adjustment of 1.0156), a wage index of 0.8594, and a rural adjustment of 14.9 percent. Facility B, an urban teaching hospital, has a DSH percentage of 15 percent (which would result in a LIP adjustment of 1.0454 percent), a wage index of 0.8695, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the prospective payment, we begin by taking the unadjusted prospective payment rate for

CMG 0104 (without comorbidities) from Table 7. Then, we multiply the labor-related share for FY 2022 (72.9 percent) described in section VI.C. of this final rule by the unadjusted prospective payment rate. To determine the non-labor portion of the prospective payment rate, we subtract the labor portion of the Federal payment from the unadjusted prospective payment.

To compute the wage-adjusted prospective payment, we multiply the labor portion of the federal payment by the appropriate wage index located in the applicable wage index table. This table is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html.*

The resulting figure is the wage-adjusted labor amount. Next, we compute the wage-adjusted Federal payment by adding the wage-adjusted labor amount to the non-labor portion of the Federal payment.

Adjusting the wage-adjusted Federal payment by the facility-level adjustments involves several steps. First, we take the wage-adjusted prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Second, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.0784, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted prospective payment rates. Table 7 illustrates the components of the adjusted payment calculation.

TABLE 7: Example of Computing the FY 2022 IRF Prospective Payment

Steps		Rural Facility A (Spencer Co., IN)		Urban Facility B (Harrison Co., IN)	
1	Unadjusted Payment		$27,571.93		$27,571.93
2	Labor Share	X	0.729	X	0.729
3	Labor Portion of Payment	=	$20,099.94	=	$20,099.94
4	CBSA-Based Wage Index \	X	0.8594	X	0.8695
5	Wage-Adjusted Amount	=	$17,273.89	=	$17,476.90
6	Non-Labor Amount	+	$7,471.99	+	$7,471.99
7	Wage-Adjusted Payment	=	$24,745.88	=	$24,948.89
8	Rural Adjustment	X	1.149	X	1.000
9	Wage- and Rural-Adjusted Payment	=	$28,433.01	=	$24,948.89
10	LIP Adjustment	X	1.0156	X	1.0454
11	Wage-, Rural- and LIP-Adjusted Payment	=	$28,876.57	=	$26,081.57
12	Wage- and Rural-Adjusted Payment		$28.433.01		$24,948.89
13	Teaching Status Adjustment	X	0	X	0.0784
14	Teaching Status Adjustment Amount	=	$0.00	=	$1,955.99
15	Wage-, Rural-, and LIP-Adjusted Payment	+	$28,876.57	+	$26,081.57
16	Total Adjusted Payment	=	$28,876.57	=	$28,037.56

Thus, the adjusted payment for Facility A would be $28,876.57, and the adjusted payment for Facility B would be $28,037.56.

VII. Update to Payments for High-Cost Outliers Under the IRF PPS for FY 2022

A. Update to the Outlier Threshold Amount for FY 2022

Section 1886(j)(4) of the Act provides the Secretary with the authority to make payments in addition to the basic IRF prospective payments for cases incurring extraordinarily high costs. A case qualifies for an outlier payment if the estimated cost of the case exceeds the adjusted outlier threshold. We calculate the adjusted outlier threshold by adding the IRF PPS payment for the case (that is, the CMG payment adjusted by all of the relevant facility-level adjustments) and the adjusted threshold amount (also adjusted by all of the relevant facility-level adjustments). Then, we calculate the estimated cost of a case by multiplying the IRF's overall CCR by the Medicare allowable covered charge. If the estimated cost of the case is higher than the adjusted outlier threshold, we make an outlier payment for the case equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold.

In the FY 2002 IRF PPS final rule (66 FR 41362 through 41363), we discussed our rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the FY 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs of caring for high-cost patients, while still providing for adequate payments for all other (non-high cost outlier) cases.

Subsequently, we updated the IRF outlier threshold amount in the FYs 2006 through 2021 IRF PPS final rules and the FY 2011 and FY 2013 notices (70 FR 47880, 71 FR 48354, 72 FR 44284, 73 FR 46370, 74 FR 39762, 75 FR 42836, 76 FR 47836, 76 FR 59256, 77 FR 44618, 78 FR 47860, 79 FR 45872, 80 FR 47036, 81 FR 52056, 82 FR 36238, 83 FR 38514, 84 FR 39054, and 85 FR 48444, respectively) to maintain estimated outlier payments at 3 percent of total estimated payments. We also stated in the FY 2009 final rule (73 FR 46370 at 46385) that we would continue to analyze the estimated outlier payments for subsequent years and adjust the outlier threshold amount as appropriate to maintain the 3 percent target.

To update the IRF outlier threshold amount for FY 2022, we proposed to use FY 2020 claims data and the same methodology that we used to set the initial outlier threshold amount in the FY 2002 IRF PPS final rule (66 FR 41316 and 41362 through 41363), which is also the same methodology that we used to update the outlier threshold amounts for FYs 2006 through 2021. The outlier

threshold is calculated by simulating aggregate payments and using an iterative process to determine a threshold that results in outlier payments being equal to 3 percent of total payments under the simulation. To determine the outlier threshold for FY 2022, we estimated the amount of FY 2022 IRF PPS aggregate and outlier payments using the most recent claims available (FY 2020) and the proposed FY 2022 standard payment conversion factor, labor-related share, and wage indexes, incorporating any applicable budget-neutrality adjustment factors. The outlier threshold is adjusted either up or down in this simulation until the estimated outlier payments equal 3 percent of the estimated aggregate payments. Based on an analysis of the preliminary data used for the proposed rule, we estimated that IRF outlier payments as a percentage of total estimated payments would be approximately 3.3 percent in FY 2021. Therefore, we proposed to update the outlier threshold amount from $7,906 for FY 2021 to $9,192 for FY 2022 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2022.

We note that, as we typically do, we updated our data between the FY 2022 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data includes a more complete set of claims for FY 2020. Based on our analysis using this updated data, we continue to estimate that IRF outlier payments as a percentage of total estimated payments are approximately 3.4 percent in FY 2021. Therefore, we will update the outlier threshold amount from $7,906 for FY 2021 to $9,491 for FY 2022 to account for the increases in IRF PPS payments and estimated costs and to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2022.

The comments received on the proposed update to the FY 2022 outlier threshold amount to maintain estimated outlier payments at approximately 3 percent of total estimated IRF payments and our responses are summarized below.

Comment: Commenters were generally supportive of the update to the outlier threshold. However, one commenter suggested that CMS consider policies that would better target outlier payments, such as placing a 10 percent cap on the amount of outlier payments any IRF could receive or lowering the 3 percent outlier pool. Additionally, another commenter suggested that any outlier change should be limited to no more than plus or minus 5 percent in any given year.

Response: We thank the commenters for their support of the update to the outlier threshold. We continue to believe that maintaining the outlier pool at 3 percent of aggregate IRF payments optimizes the extent to which we can reduce financial risk to IRFs of caring for highest-cost patients, while still providing for adequate payments for all other nonoutlier cases. However, as we did not propose changes to this methodology, these comments are outside the scope of this final rule. We will continue to monitor our IRF outlier policies to ensure that they continue to compensate IRFs appropriately. We refer readers to the FY 2002 IRF PPS final rule (66 FR 41316, 41362 through 41363) for more information regarding the rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments.

Comment: One commenter asked CMS to provide further analysis and expand upon the relationship between COVID–19 related claims in the outlier calculations so that stakeholders could better understand CMS's perspective on the continuing impact of public health emergency claims from both the prior and current fiscal years on FY 2022 payments and beyond.

Response: We thank the commenter and appreciate the suggestion regarding further analysis to be conducted on outlier payments and COVID–19 claim interactions. We examined the relative weight values calculated both including and excluding cases associated with a COVID–19 ICD–10 diagnosis code. This analysis indicated that the majority of the changes in relative weight value would be less than 1 percent when COVID cases were removed.

Comment: Several commenters expressed concerns that the use of 2020 data in establishing the fixed-loss threshold would result in an excessively high fixed loss threshold that may be disconnected from the expected characteristics of patients in FY 2022 as the pandemic continues to subside. These commenters noted that the net result would be a substantial underpayment of outliers. The commenters requested that CMS freeze the fixed-loss threshold amount at the FY 2021 level, which was based on FY 2019 claims.

Response: We do not believe that freezing the fixed-loss threshold at the FY 2021 level is appropriate because to do so would fail to address the fact that we estimate for FY 2021 that we are overpaying by 0.4 percent the established outlier pool of 3 percent for the IRF PPS. As discussed previously, providers have access to Provider Relief Funds to assist with COVID–19 related costs, and it is unclear why IRFs would have incurred higher costs during the pandemic that were not COVID–19 related. We issued several IRF waivers to assist with the COVID–19 pandemic that, if anything, would have significantly lowered the costs of caring for patients in the IRF setting. Thus, we do not find any justification for continuing to overpay the established outlier pool of 3 percent.

Further, in FY 2022, we believe that IRFs, as the leader in rehabilitation services, will be very involved in treating the sequela of the COVID–19 infection in patients. Also, we believe that many of the infection control measures, such as personal protective equipment, private room and isolation protocols, and provision of therapies in a patient's room rather than a group setting, will continue to be used throughout IRFs in FY 2022 as new variants of COVID–19 emerge.

Comparing the outlier threshold adjustments in prior years, we continue to believe that maintaining the outlier pool at 3 percent of aggregate IRF payments optimizes the extent to which we can reduce financial risk to IRFs of caring for highest-cost patients, while still providing for adequate payments for all other non-outlier cases.

We will continue to monitor our IRF outlier policies to ensure that they continue to compensate IRFs appropriately. If we find any overpayments or underpayments in IRF outliers, we will continue to adjust the IRF outlier threshold amount appropriately to maintain IRF outlier payments at 3 percent of total IRF payments in future rulemaking cycles.

After consideration of the comments received and taking into account the most recent available data, we are finalizing the outlier threshold amount of $9,491 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2022.

B. Update to the IRF Cost-to-Charge Ratio Ceiling and Urban/Rural Averages for FY 2022

CCRs are used to adjust charges from Medicare claims to costs and are computed annually from facility-specific data obtained from MCRs. IRF specific CCRs are used in the development of the CMG relative weights and the calculation of outlier payments under the IRF PPS. In

accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we proposed to apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we proposed to update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2022, based on analysis of the most recent data available. We apply the national urban and rural CCRs in the following situations:

- New IRFs that have not yet submitted their first MCR.
- IRFs whose overall CCR is in excess of the national CCR ceiling for FY 2022, as discussed below in this section.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2022, we proposed to estimate a national average CCR of 0.478 for rural IRFs, which we calculated by taking an average of the CCRs for all rural IRFs using their most recently submitted cost report data. Similarly, we proposed to estimate a national average CCR of 0.393 for urban IRFs, which we calculated by taking an average of the CCRs for all urban IRFs using their most recently submitted cost report data. We apply weights to both of these averages using the IRFs' estimated costs, meaning that the CCRs of IRFs with higher total costs factor more heavily into the averages than the CCRs of IRFs with lower total costs. For this final rule, we have used the most recent available cost report data (FY 2019). This includes all IRFs whose cost reporting periods begin on or after October 1, 2018, and before October 1, 2019. If, for any IRF, the FY 2019 cost report was missing or had an ''as submitted'' status, we used data from a previous FY's (that is, FY 2004 through FY 2018) settled cost report for that IRF. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care. We proposed that if more recent data become available after the publication of the proposed rule and before the publication of the final rule, we would use such data to determine the FY 2022 national average rural and urban CCRs and the national CCR ceiling in the final rule. Using updated FY 2019 cost report data for this final rule, we estimate a national average CCR of 0.478 for rural IRFs, and a national average CCR of 0.394 for urban IRFs.

In accordance with past practice, we proposed to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, we proposed a national CCR ceiling of 1.34 for FY 2022. This means that, if an individual IRF's CCR were to exceed this ceiling of 1.34 for FY 2022, we will replace the IRF's CCR with the appropriate proposed national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculated the proposed national CCR ceiling by:

Step 1. Taking the national average CCR (weighted by each IRF's total costs, as previously discussed) of all IRFs for which we have sufficient cost report data (both rural and urban IRFs combined).

Step 2. Estimating the standard deviation of the national average CCR computed in step 1.

Step 3. Multiplying the standard deviation of the national average CCR computed in step 2 by a factor of 3 to compute a statistically significant reliable ceiling.

Step 4. Adding the result from step 3 to the national average CCR of all IRFs for which we have sufficient cost report data, from step 1.

Using the updated FY 2019 cost report data for this final rule, we estimate a national average CCR ceiling of 1.35, using the same methodology.

We invited public comment on the proposed update to the IRF CCR ceiling and the urban/rural averages for FY 2022.

However, we did not receive any comments on the proposed revisions to the IRF CCR ceiling and the urban/rural averages for FY 2022, and therefore, we are finalizing the national average urban CCR at 0.394, the national average rural CCR at 0.478, and the national average CCR ceiling at 1.35 for FY 2022.

VIII. Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP)

A. Background and Statutory Authority

The Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) is authorized by section 1886(j)(7) of the Act, and it applies to freestanding IRFs, as well as inpatient rehabilitation units of hospitals or Critical Access Hospitals (CAHs) paid by Medicare under the IRF PPS. Under the IRF QRP, the Secretary must reduce by 2 percentage points the annual increase factor for discharges occurring during a fiscal year for any IRF that does not submit data in accordance with the IRF QRP requirements established by the Secretary. For more information on the background and statutory authority for the IRF QRP, we refer readers to the FY 2012 IRF PPS final rule (76 FR 47873 through 47874), the CY 2013 Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Payment Systems and Quality Reporting Programs final rule (77 FR 68500 through 68503), the FY 2014 IRF PPS final rule (78 FR 47902), the FY 2015 IRF PPS final rule (79 FR 45908), the FY 2016 IRF PPS final rule (80 FR 47080 through 47083), the FY 2017 IRF PPS final rule (81 FR 52080 through 52081), the FY 2018 IRF PPS final rule (82 FR 36269 through 36270), the FY 2019 IRF PPS final rule (83 FR 38555 through 38556), and the FY 2020 IRF PPS final rule (84 FR 39054 through 39165).

B. General Considerations Used for the Selection of Measures for the IRF QRP

For a detailed discussion of the considerations we use for the selection of IRF QRP quality, resource use, or other measures, we refer readers to the FY 2016 IRF PPS final rule (80 FR 47083 through 47084).

1. Quality Measures Currently Adopted for the FY 2022 IRF QRP

The IRF QRP currently has 17 measures for the FY 2022 program year, which are set out in Table 8.

TABLE 8: Quality Measures Currently Adopted for the FY 2022 IRF QRP

Short Name	Measure Name & Data Source
IRF-PAI Assessment-Based Measures	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility	IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).
Discharge Mobility Score	IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
Change in Self-Care	IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).
Discharge Self-Care Score	IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP).
TOH-Provider*	Transfer of Health Information to the Provider–Post-Acute Care (PAC).
TOH-Patient*	Transfer of Health Information to the Patient Post-Acute Care (PAC).
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection Outcome Measure (NQF #0138).
CDI	National Healthcare Safety Network (NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).
Claims-Based	
MSPB IRF	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) IRF QRP (NQF #3561).
DTC	Discharge to Community–PAC IRF QRP (NQF #3479).
PPR 30 day	Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP.
PPR Within Stay	Potentially Preventable Within Stay Readmission Measure for IRFs.

*In response to the public health emergency (PHE) for the Coronavirus Disease 2019 (COVID-19), CMS released an interim final rule (85 FR 27595 through 27596) which delayed the compliance date for the collection and reporting of the Transfer of Health Information measures for at least 1 full fiscal year after the end of the PHE.

C. IRF QRP Quality Measures Beginning With the FY 2023 IRF QRP

Section 1899B(h)(1) of the Act permits the Secretary to remove, suspend, or add quality measures or resource use or other measures described in sections 1899B(c)(1) and section 1899B(d)(1) of the Act respectively, so long as the Secretary publishes in the **Federal Register** (with a notice and comment period) a justification for such removal, suspension, or addition. We proposed to adopt one new measure: The COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) [5] measure as an ''other'' measure under the resource use or other measure domain under section 1899B(d)(1) of the Act beginning with the FY 2023 IRF QRP. In accordance with section 1899B(a)(1)(B) of the Act, the data used to calculate this measure is standardized and interoperable. The proposed measure supports the Meaningful Measures domain of Promote Effective Prevention and Treatment of Chronic Disease. CMS identified the measure's concept as a priority in response to the current public health crisis. This process measure was developed with the Centers for Disease Control and Prevention (CDC) to track COVID–19 vaccination Coverage among HCP in the IRF setting. This measure is described in more detail below.

In addition, we proposed to update the denominator for one measure, the Transfer of Health (TOH) Information to the Patient–Post-Acute Care (PAC) measure to exclude patients discharged home under the care of an organized home health service or hospice.

1. COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2023 IRF QRP

a. Background

On January 31, 2020, the Secretary of the U.S. Department Health and Human Services declared a public health emergency (PHE) for the United States in response to the global outbreak of

[5] The measure steward changed the name of the measure from SARS–CoV–2 Vaccination Coverage among Healthcare Personnel to COVID–19 Vaccination Coverage among Healthcare Personnel. There were no changes to the measure itself, other than the name change.

SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[6] COVID–19 is a contagious respiratory infection[7] that can cause serious illness and death. Older individuals, racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[8 9] As stated in the proposed rule, as of March 31, 2021, the U.S. reported over 30 million cases of COVID–19 and over 548,000 COVID–19 deaths.[10] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[11] In December 2020 and January 2021, media outlets reported that more than 100,000 Americans were in the hospital with COVID–19.[12] As of July 21, 2021, the U.S. has reported over 33 million cases of COVID–19 and over 600,000 COVID–19 deaths.[13]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[14] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[15] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface.[16]

According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[17] Subsequent to the publication of the proposed rule, the CDC has confirmed that the three main ways that COVID–19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.[18] Personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, but COVID–19 can still spread between health care personnel (HCP) and patients given the close contact that may occur during the provision of care.[19] The CDC has emphasized that health care settings, including IRFs, can be high-risk places for COVID–19 exposure and transmission.[20]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[21]

On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the United States.[22] Subsequently, the FDA issued EUAs for additional COVID–19 vaccines. In issuing these EUAs, the FDA determined that it was reasonable to conclude that the known and potential benefits of each vaccine, when used as authorized to prevent COVID–19, outweighed its known and potential risks.[23 24 25]

As part of its national strategy to address COVID–19, the Biden administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[26] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including healthcare personnel (HCP),[27] and individuals at highest risk for developing severe illness from COVID–19.[28] For example, the CDC's Advisory

[6] U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[7] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[8] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[9] Centers for Disease Control and Prevention (2021). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[10] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[11] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895.* Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.*

[12] NPR. U.S. Hits 100,000 COVID–19 Hospitalizations, Breaks Daily Death Record. Dec. 2, 2020. Accessed on December 17, 2020 at *https://www.npr.org/sections/coronavirus-live-updates/2020/12/02/941902471/u-s-hits-100-000-covid-19-hospitalizations-breaks-daily-death-record;* The Wall Street Journal. Coronavirus Live Updates: U.S. Hospitalizations, Newly Reported Cases, Deaths Edge Downward. Accessed on January 11 at *https://www.wsj.com/livecoverage/covid-2021-01-11.*

[13] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[14] Centers for Disease Control and Prevention. (2021). COVID–19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[15] Centers for Disease Control and Prevention (2021). COVID–19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[16] Centers for Disease Control and Prevention (2021). COVID–19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[17] Centers for Disease Control and Prevention. (2020). Clinical Questions about COVID–19: Questions and Answers. Accessed on December 2, 2020 at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html.*

[18] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on July 15, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[19] Centers for Disease Control and Prevention. (2020). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on December 2 at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html.*

[20] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[21] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[22] U.S. Food and Drug Administration. (2021). Pfizer-BioNTech COVID–19 Vaccine. Available at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.*

[23] Ibid.

[24] U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download.*

[25] U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.*

[26] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. March 29, 2021. Accessed at *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/.*

[27] Centers for Disease Control and Prevention. Glossary of Terms. *https://cdc.gov/infectioncontrol/guidelines/healthcare-personnel/appendix/terminology.html.*

[28] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf;* Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at *https://*

Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity.[29] Research suggests most states followed this recommendation,[30] and HCP began receiving the vaccine in mid-December of 2020.[31] Subsequent to the publication of the IRF PPS proposed rule, on June 3, 2021 the White House confirmed that there was sufficient vaccine supply for all Americans.[32]

HCP are at risk of carrying COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, and the general public. We believe it is important to require that IRFs report COVID–19 HCP vaccination in order to assess whether they are taking steps to limit the spread of COVID–19 among their HCP, reduce the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of IRFs to continue serving their communities throughout the PHE and beyond.

We also believe that publishing facility level COVID–19 HCP vaccination rates on Care Compare would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures framework, the COVID–19 Vaccination Coverage among Healthcare Personnel measure addresses the quality priority of ''Promote Effective Prevention & Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

Therefore, we proposed a new measure, COVID–19 Vaccination Coverage among HCP to assess the proportion of an IRF's healthcare workforce that has been vaccinated against COVID–19.

b. Stakeholder Input

In the development and specification of the measure, a transparent process was employed to seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, under section 1890A of the Act.[33] To meet this requirement, the following opportunity was provided for stakeholder input.

The pre-rule making process includes making publicly available a list of quality and efficiency measures, called the Measures Under Consideration (MUC) List that the Secretary is considering adopting, through federal rulemaking process, for use in Medicare program(s). This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list. The COVID–19 Vaccination Coverage among Healthcare Personnel measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020''.[34] Five comments were received from industry stakeholders during the pre-rulemaking process on the COVID–19 Vaccination Coverage among HCP measure, and support was mixed. Commenters generally supported the concept of the measure. However, there was concern about the availability of the vaccine and measure definition for HCP, and some commenters encouraged CMS to continue to update the measure as new evidence comes in.

c. Measure Applications Partnership (MAP) Review

When the Measure Applications Partnership (MAP) Post-Acute Care/Long-Term Care (PAC–LTC) Workgroup convened on January 11, 2021, it reviewed the MUC List and the COVID–19 Vaccination Coverage among HCP measure. The MAP recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the IRF QRP measure set by providing transparency about an important COVID–19 intervention to help limit COVID–19 infections.[35] The MAP also stated that collecting information on COVID–19 vaccination Coverage among healthcare personnel and providing feedback to facilities would allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing rates of COVID–19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness.[36]

In its preliminary recommendations, the MAP PAC–LTC Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[37] To mitigate its concerns, the MAP believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[38] Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 Vaccination Coverage among Healthcare Personnel measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measures back to the MAP once the specifications are further clarified. The final MAP report is available at *http://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

In response to the MAP request for CMS to bring the measure back once the specifications were further clarified, CMS met with the MAP Coordinating Committee on March 15, 2021. First, CMS and CDC clarified the alignment of the COVID–19 Vaccination Coverage among HCP with the Influenza Vaccination among HCP (NQF #0431), an NQF-endorsed measure since 2012. The COVID–19 Vaccination Coverage among HCP measure is calculated using the same approach as the Influenza Vaccination among HCP measure.[39] The

www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

[29] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[30] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.*

[31] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.*

[32] Press Briefing by White House COVID–19 Response Team and Public Health Officials | The White House. Accessed on July 21, 2021 at *https://www.whitehouse.gov/briefing-room/press-briefings/2021/06/03/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-40/.*

[33] Centers for Medicare & Medicaid Services. Pre-rulemaking. Accessed at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking.*

[34] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 12, 2021.

[35] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on February 3, 2021 at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.*

[36] Ibid.

[37] Ibid.

[38] Ibid.

[39] The Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which

Continued

approach to identifying HCPs eligible for the COVID–19 vaccination is analogous to those used in the NQF endorsed flu measure which underwent rigorous review from technical experts about the validity of that approach and for which ultimately received NQF endorsement. More recently, prospective cohorts of health care personnel, first responders, and other essential and frontline workers over 13 weeks in eight U.S. locations confirmed that authorized COVID–19 vaccines are highly effective in real-world conditions. Vaccine effectiveness of full immunization with two doses of vaccines was 90 percent.[40]

Additionally, to support the measure's data element validity, CDC conducted testing of the COVID–19 vaccination numerator using data collected through the NHSN and independently reported through the Federal Pharmacy Partnership for Long-term Care Program for delivering vaccines to long-term care facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination, the number of HCP vaccinated in approximately 1,200 facilities, which had data from both systems, the number of HCP vaccinated was highly correlated between these two systems with a correlation coefficient of nearly 90 percent in the second 2 weeks of reporting. Of note, assessment of data element reliability may not be required by NQF if data element validity is demonstrated.[41] In addition, for assessing the validity of new performance measure score (in this case, percentage COVID–19 vaccination coverage), NQF allows assessment by face validity (subjective determination by experts that the measure appears to reflect quality of care, done through a systematic and transparent process)[42] and the MAP concurred with face validity of the measure of COVID–19 vaccination coverage. Materials from the March 15, 2021 MAP Coordinating Committee meeting are on the NQF website at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

This measure is not NQF endorsed, but CMS, in collaboration with the CDC, plans to submit the measure for NQF endorsement in the future.

d. Competing and Related Measures

Section 1886(j)(7)(D)(i) of the Act requires that, absent an exception under section 1886(j)(7)(D)(ii) of the Act, measures specified by the Secretary under section 1886(j)(7)(D) of the Act be endorsed by the entity with a contract under section 1890(a) of the Act, currently the National Quality Forum (NQF). In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1886(j)(7)(D)(ii) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Section 1899B(e)(2)(A) of the Act requires that, subject to section 1899B(e)(2)(B) of the Act, each measure specified by the Secretary under section 1899B of the Act be endorsed by the entity with a contract under section 1890(a) of the Act. However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed COVID–19 Vaccination Coverage among HCP measure is not currently NQF endorsed and has not been submitted to the NQF for consideration, so we considered whether there are other available measures that assess COVID–19 vaccinations among HCP. After review of the NQF's consensus-endorsed measures, we were unable to identify any NQF endorsed measures for IRFs focused on capturing COVID–19 vaccination coverage of HCP and we found no other feasible and practical measure on the topic of COVID–19 vaccination Coverage among HCP, and we found no other feasible and practical measure on the topic of COVID–19 vaccination Coverage among HCP. The only other vaccination coverage of HCP measure found was the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which is NQF endorsed and was adopted in the IRF QRP in the FY 2014 IRF PPS Final Rule (78 FR 47905 through 47906).

Given the novel nature of the SARS–CoV–2 virus, and the significant and immediate risk it poses in IRFs, we believed it was necessary to propose the measure as soon as possible. Therefore, after consideration of other available measures that assess COVID–19 vaccination rates among HCP, we believe the exception under section 1899B(e)(2)(B) of the Act applies. This proposed measure has the potential to generate actionable data on vaccination rates that can be used to target quality improvement among IRF providers.

e. Quality Measure Calculation

The COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure is a process measure developed by the CDC to track COVID–19 vaccination Coverage among HCP in facilities such as IRFs. Since this proposed measure is a process measure, rather than an outcome measure, it does not require risk-adjustment.

The denominator would be the number of HCP eligible to work in the IRF for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination, that are described by the CDC.[43]

The numerator would be the cumulative number of HCP eligible to work in the IRF for at least one day during the reporting period and who received a complete vaccination course against SARS–CoV–2. A complete vaccination course may require one or more doses depending on the specific vaccine used. The finalized measure specifications are available on the CDC website at *https://www.cdc.gov/nhsn/nqf/index.html.*

We proposed that IRFs would submit data for the measure through the CDC/NHSN data collection and submission framework.[44] This framework is currently used for reporting the CAUTI (NQF #0138) and Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measures. IRFs would use the COVID–19 vaccination data reporting module in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible who have worked at the facility

is NQF endorsed and was adopted in the IRF QRP in the FY 2014 IRF PPS Final Rule (78 FR 47905 through 47906), and in the LTCH QRP in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53630 through 53631).

[40] Centers for Disease Control and Preventions. Morbidity and Mortality Weekly Report. March 29, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm?s_cid=mm7013e3_w.*

[41] National Quality Form. Key Points for Evaluating Scientific Acceptability. Revised January 3, 2020. *https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Docs/Evaluation_Guidance.aspx#:~:text.*

[42] Ibid.

[43] Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United Sates, Appendix B. Accessed at *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B.*

[44] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

that week (denominator) and the number of those HCP who have received a completed COVID–19 vaccination course (numerator). IRFs would submit COVID–19 vaccination data for at least 1 week each month. If IRFs submit more than one week of data in a month, the most recent week's data would be used for measure calculation purposes. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the three monthly modules reported for the quarter. This quarterly rate would be publicly reported on the Care Compare website. Subsequent to the first refresh, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four full quarters of data is reached. Thereafter, the measure would be reported using four rolling quarters of data on Care Compare.

For purposes of submitting data to CMS for the FY 2023 IRF QRP, IRFs would be required to submit data for the period October 1, 2021 through December 31, 2021. Following the data submission quarter for the FY 2023 IRF QRP, subsequent compliance for the IRF QRP would be based on four quarters of such data submission. For more information on the measure's proposed public reporting period, we refer readers to section VII.G.2 of the proposed rule.

We invited public comment on our proposal to add a new measure, COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure, to the IRF QRP beginning with the FY 2023 IRF QRP.

The following is a summary of the public comments received on the proposed revisions to add a new measure, COVID–19 Vaccination Coverage among HCP measure, to the IRF QRP beginning with the FY 2023 IRF QRP, and our responses:

Comment: A number of organizations, including provider associations and patient advocacy groups, supported the proposal to adopt the COVID–19 Vaccination Coverage among HCP measure for the IRF QRP. Commenters agreed that the measure is vitally important to protect the health and well-being of older adults in IRFs and reporting of this measure through the NHSN would help to ensure transparency and accountability in community infection prevention and control efforts. The commenters supported the idea that reporting of HCP vaccination rates helps inform patient and caregiver choices when considering IRFs from which to seek care, particularly for those at high risk for developing serious complications from COVID–19. Another commenter noted that reporting COVID–19 HCP vaccination rates would provide greater transparency to federal officials and other stakeholders seeking to effectively target vaccine hesitancy and resources related to the COVID–19 vaccines. One commenter noted that vaccinations are particularly important because the nature of care settings like IRFs makes other COVID–19 transmission mitigation strategies (for example, social distancing) much less effective.

Response: We thank the commenters for their support and agree that the COVID–19 Vaccination Coverage among HCP measure is critically important to the protection of health and well-being of older adults in IRFs, and that reporting this measure will help to ensure transparency and accountability in community infection prevention and control efforts. We also agree that the nature of care settings like IRFs makes other COVID–19 transmission mitigation strategies less effective, which makes COVID–19 vaccinations of HCP in this setting especially important. The CDC has also emphasized that healthcare settings, including IRFs, can be high-risk places for COVID–19 exposure and transmission and notes that COVID–19 can spread between HCP and patients given the close contact that may occur during the provision of care.[45]

Although we received a number of comments in support of the measure's concept as well as the need to encourage widespread vaccination among HCP, some commenters expressed concerns with the measure, including administrative burden, lack of access to the vaccine, concerns that staff may be intimidated into receiving the vaccine, the lack of certainty about whether a booster vaccination will be necessary, concern that the vaccinations have not received full FDA approval, and finally that the measure is not NQF endorsed. We will address each of these comments below.

Comment: Several commenters expressed concern over the potential for inequality among providers because vaccines are not equally available across the nation. They point out that the type of vaccine available to them is out of their control and since the availability of the single-dose vaccines may be different across the country, some providers would be at a disadvantage because of the 4-week waiting period between doses of the two-dose vaccines to reach complete vaccination status. Some providers were concerned about vaccine availability. These commenters pointed out that at times the COVID–19 vaccine supply chain has been disrupted and believe the measure should not be implemented until there is a more definitive understanding of the future supply of vaccines.

Response: As part of its national strategy to address COVID–19, the current administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy. The goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one. While we acknowledge that vaccine supply was initially limited, more than 20 states are no longer ordering all the vaccine doses allocated to them due to decline in demand,[46] and more than 1,000 counties are reporting a surplus of vaccine appointments.[47] We understand that vaccine availability may vary based on location, and vaccination and medical staff authorized to administer the vaccination may not be readily available in all areas. Supply distribution is the responsibility of each state, and IRFs should continue to consult state and local health departments to understand the range of options for how vaccines can be made available to patients and staff.

As discussed in section VIII.C.1.e of this final rule, we proposed that IRFs would submit data for the COVID–19 vaccination Coverage among HCP measure data for at least 1 week each month. If IRFs submit more than 1 week of data in a month, the most recent week's data would be used for measure calculation purposes. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the three monthly modules reported for the quarter. This quarterly rate would be publicly reported on the Care Compare website. As a result, there will be time within the quarter for persons receiving the two-dose vaccine to reach complete vaccination status.

Comment: Several commenters were concerned about the effect potential booster shots could have on the definition of a ''complete vaccination course,'' and raised questions about

[45] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[46] CBS News. More than 20 States Not Ordering All Available Doses as COVID–19 Vaccinations Slow. May 3, 2021. Available at *https://www.cbsnews.com/news/covid-19-vaccine-doses-states/*. Accessed June 24, 2021.

[47] GoodRx. From Shortage to Surplus: A Growing Number of U.S. Counties Have Vacant COVID–19 Vaccine Appointments. April 20, 2021. Available at *https://www.goodrx.com/;blog/covid-19-vaccine-surplus-vacant-appointments/*. Accessed June 24, 2021.

whether a booster shot would be needed, the timing of such a shot, and at what intervals. They pointed out that it could complicate the tracking of the measure, while others questioned how booster shots would factor into reporting requirements. Commenters requested that CMS clarify how the potential need for ''booster'' vaccinations would be accounted for in IRFs going forward. A commenter noted that in the FY 2022 Inpatient Prospective Payment System (IPPS) proposed rule, CMS states that the numerator would be calculated based on HCP who received a completed vaccination course ''since the vaccine was first available or on a repeated interval if revaccination is recommended.'' Since this language is not included in the FY 2022 IRF PPS proposed rule, they requested clarification on how evolving vaccine recommendations will be accounted for in this proposed measure.

Response: The COVID–19 Vaccination Coverage among HCP measure is a measure of a completed COVID–19 vaccination course as defined in section VIII.C.1.e. of this final rule. A complete vaccination course may require one or more doses depending on the specific vaccine used. Currently, the need for COVID–19 booster doses has not been established, and no additional doses are currently recommended for HCP.[48] However, we believe that the numerator is sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' and therefore the measure is sufficiently specified to address boosters.

Comment: We received several comments posing questions about the uncertainty the provider community believes about the future of the COVID–19 vaccination. Commenters voiced concern about the uncertainty of how long the vaccines confer immunity. They point to the amount of misinformation that has been and is still currently being spread about COVID–19 and the vaccinations.

Response: We acknowledge the science relating to the SARS–CoV–2 virus continues to evolve. It is another reason the COVID–19 Vaccination Coverage among HCP measure is so important. Population immunity means that enough people in a community are protected from getting a disease because they have already had the disease or because they have been vaccinated. Population immunity makes it hard for the disease to spread from person to person.[49]

We are still learning how effective the vaccines are against new variants of the virus that causes COVID–19. Current evidence suggests that the COVID–19 vaccines authorized for use in the United States offer protection against most variants currently spreading in the United States.[50] The CDC will continue to monitor how vaccines are working to see if variants have any impact on how well COVID–19 vaccines work in real-world conditions.

Comment: Because the vaccine is new, several commenters suggested that CMS not adopt the measure until more is known about SARS–CoV–2. Other commenters urged CMS to either make the measure voluntary for the FY 2023 program, or delay implementation by at least 1 year.

Response: We believe it is important that all IRFs report COVID–19 Vaccination Coverage among HCP as soon as possible in order to assess the potential spread of COVID–19 among their HCP and within their facilities to help sustain the ability of IRFs to continue serving their communities throughout the PHE and beyond. Allowing IRFs to voluntarily report may result in selective reporting among high-performing facilities, which would reduce the usefulness of the publicly reported data. Because of the ongoing PHE for COVID–19 and risk of infection transmissions in the IRF population, this measure will be informative to beneficiaries and consumers who receive inpatient rehabilitation services from IRFs.

Comment: Commenters pointed out that there is still a degree of vaccine hesitancy remaining among the general population as well as hospital staff. They believe the lack of certainty could create an unnecessary burden on IRFs until the vaccines receive FDA approval or there is some equivalent guidance from the federal government clarifying how IRFs should proceed with mandating vaccinations.

Response: We reiterate that the COVID–19 vaccines are authorized by FDA for use through Emergency Use Authorizations (EUAs). We refer readers to the FDA website for additional information related to FDA's process for evaluating an EUA request at *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.* Additionally, two of the three vaccines authorized for emergency use are shown to be 90 to 95 percent effective in preventing COVID–19 in persons without prior infection, and are equally effective across a variety of characteristics, including age, gender, race, ethnicity, and body mass index or presence of other medical conditions.[51] In clinical trials, the Pfizer vaccine was 100 percent effective at preventing severe disease. The third vaccine authorized for emergency use demonstrates it is 93.1 percent effective at preventing COVID–19 hospitalization and 75 percent effective against all-cause death.[52] The FDA is closely monitoring the safety of the COVID–19 vaccines authorized for emergency use.

We believe it is critical to measure staff vaccination rates among IRFs even as vaccinations become more common, especially in light of the vaccine hesitancy the commenters have pointed out. As reported by Medscape Medical News on June 28, 2021,[53] federal data show that one in four hospital workers across the United states are still unvaccinated, and only one in every three hospital workers are vaccinated in the nation's 50 largest health systems. Moreover, the adoption of this measure does not mandate or require that HCP complete a COVID–19 vaccination course. Even if IRFs have limited control over the vaccination status of their employees, the information collected by this measure is vitally important and useful to stakeholders.

Comment: We received several comments stating that while the COVID–19 Vaccination Coverage among HCP measure does not directly compel IRFs to ensure that their employees are vaccinated, publicly reporting performance on this measure might

[48] Centers for Disease Control and Prevention. Vaccine Administration. Available at *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.* Accessed June 25, 2021.

[49] Centers for Disease Control and Prevention. Population Immunity. Available at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html.* Accessed June 25, 2021.

[50] Centers for Disease Control and Prevention. Covid–19 vaccines and new variants. Available at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/work.html#:~:text=COVID%2D19%20vaccines%20and%20new%20variants%20of%20the%20virus&text=Current%20data%20suggest%20that%20COVID,after%20they%20are%20fully%20vaccinated.* Accessed June 25, 2021.

[51] Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID–19 Among Hospitalized Adults Aged ≥65 Years—United States, January–March 2021. Morbidity and Mortality Weekly Report (MMWR). May 7, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e1.htm?s_cid=mm7018e1_w.* Accessed July 19, 2021.

[52] The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID–19 Vaccine—United States, February 2021. Morbidity and Mortality Weekly Report (MMWR). March 5, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7009e4.htm.* Accessed July 19, 2021.

[53] Medscape. Disturbing Number of Hospital Workers Still Unvaccinated. Available at *https://www.medscape.com/viewarticle/953871.* Accessed July 13, 2021.

incent IRFs to adopt mandatory vaccination policies for their personnel. As a result, commenters suggest the measure has the potential to jeopardize an already challenged workforce, exacerbating critical workforce issues, if IRFs attempt to produce a positive performance by either mandating vaccination and/or not hiring or letting go of staff who choose not to be vaccinated. One commenter noted that multiple states have introduced or passed legislation prohibiting discrimination based on COVID–19 vaccination status. Several state legislatures have considered legislation that would prohibit an employer from forcing employees to be vaccinated for COVID–19. Other state legislatures are considering legislation to specifically authorize employer-mandated vaccinations. Commenters cautioned that IRFs unable to mandate the vaccine could be at a systematic performance disadvantage on the measure.

Response: We believe that the unprecedented risks associated with the COVID–19 PHE warrant direct attention, especially because HCP are working directly with and in close proximity to patients, but are clarifying that the COVID–19 Vaccination Coverage among HCP measure does not require providers to adopt mandatory vaccination policies. To support a comprehensive vaccine administration strategy, we encourage IRFs to voluntarily engage in the provision of appropriate and accessible education and vaccine-offering activities. Many IRFs across the country are educating staff, patients, and patient representatives, participating in vaccine distribution programs, and voluntarily reporting vaccine administration. The CDC has a number of resources [54] available to providers to assist in building vaccine confidence. CMS also has a web page to help providers, including IRFs, find resources related to the COVID–19 vaccines.[55] There are a number of toolkits and videos providers can use to stay informed and to educate their employees, patients and communities about the COVID–19 vaccines.

Consistent vaccination reporting by IRFs via the NHSN will help patients and their caregivers identify IRFs that have potential issues with vaccine confidence or slow uptake among staff. Implementation of voluntary COVID–19 vaccine education and vaccination programs in IRFs will help protect patients and staff, allowing for an expedited return to more normal routines, including timely preventive healthcare; family, caregiver, and community visitation; and group and individual activities.[56]

Regarding concerns over discrimination based on COVID–19 vaccination status, the Equal Employment Opportunity Commission (EEOC) released updated and expanded technical assistance on May 28, 2021,[57] stating that federal equal employment opportunity (EEO) laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEO considerations.

Comment: One commenter referenced new state laws restricting an employer's ability to obtain information regarding an employee's vaccination status unless it is for the purpose of determining whether the facility should implement reasonable accommodation measures to protect health and safety.

Response: We acknowledge the commenter's concern regarding state laws prohibiting providers from obtaining information regarding an employee's COVID–19 vaccination status except in certain circumstances related to health and safety. We believe, however, that obtaining COVID–19 vaccination status information is important for determining reasonable measures to protect the health and safety of not only the patients it serves, but other staff working within the facility. Within the NHSN reporting module, there is an option to select ''unknown COVID–19 vaccination status'' and providers should utilize this response for employees who choose not to disclose their status. Additionally, as mentioned in the previous comment response, the EEOC released updated and expanded technical assistance on May 28, 2021,[58] stating that federal EEO laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEO considerations.

Comment: One commenter questioned whether the proposal was in conflict with guidance from the EEOC, which states employers must provide a reasonable accommodation if an employee's sincerely held religious belief, practice, or observance prevents them from receiving the vaccination.

Response: We believe the commenter is referring to the updated and expanded technical assistance the EEOC issued on May 28, 2021.[59] CMS disagrees that the proposal conflicts with the EEOC's guidance. Specifically, the EEOC stated the federal EEO laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEO considerations. This measure is intended to report the number of HCP who have received a COVID–19 vaccination, but it does not mandate HCP to receive a COVID–19 vaccination.

Comment: One commenter questioned why this information would be used in a quality measure that impacts payments when providers cannot mandate their staff to become vaccinated. Another commenter pointed out that the potential for interstate regulatory differences raises concerns about a future employee vaccination metric in a pay-for-performance program.

Response: We proposed the COVID–19 Vaccination Coverage among HCP measure beginning with the FY 2023 IRF QRP. The IRF QRP is a pay-for-reporting program under which IRFs are not financially penalized based on measure performance, but rather on

[54] Centers for Disease Control and Prevention. Building Confidence in COVID–19 Vaccines. Available at *https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html.*

[55] Centers for Medicare and Medicaid Services. Coronovirus (COVID–19) Partner Resources. Available at *https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-resources.*

[56] Centers for Disease Control and Prevention. Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID–19 Vaccination. Available at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html.* Accessed June 26, 2021.

[57] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.* Accessed June 25, 2021.

[58] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.* Accessed June 25, 2021.

[59] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.* Accessed June 25, 2021.

their adherence to the reporting requirements.

Comment: A few commenters raised the issue of the possibility of legal risk to their organization if HCP experience an adverse event related to a vaccine, given the vaccines are not FDA-approved. They point out that this creates ethical and legal challenges to the organization.

Response: It is unclear what legal and ethical challenges the commenters are referring to, as the COVID–19 Vaccination Coverage among HCP measure does not require HCP to be vaccinated. In addition, all of the COVID–19 vaccines have been authorized by the FDA for widespread use through an EUA. We refer readers to the FDA website for additional information related to the process of vaccination vetting and approval found here: *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.*

Comment: A number of commenters stated that it is premature to begin tracking COVID–19 vaccinations because the COVID–19 vaccines are authorized through an EUA and do not have full FDA approval at this time. One provider acknowledged that they were confident in the safety and efficacy of the three current vaccine products but still find it to be incongruous to adopt a measure into federal quality reporting programs that assesses the use of a product that has not yet received full federal approval.

Response: We believe there is still risk of transmitting infections in the IRF population. COVID–19 vaccines are a crucial tool for slowing the spread of disease and death among residents, staff, and the general public. Based on the FDA's review, evaluation of the data, and its decision to authorize three vaccines for emergency use, these vaccines meet FDA's standards for an EUA for safety and effectiveness to prevent COVID–19 disease and related serious outcomes, including hospitalization and death. The combination of vaccination, universal source control (wearing masks), social distancing, and handwashing offers further protection from COVID–19.[60] Given the emergency use authorization by the FDA and the continued PHE for COVID–19, we disagree with the commenter, and believe our proposal to add the COVID–19 Vaccination Coverage among HCP measure to the IRF QRP is appropriate and necessary for patient safety.

Comment: We received numerous comments requesting that CMS delay the adoption of the COVID–19 Vaccination Coverage among HCP measure until it has received NQF endorsement. These commenters expressed concern that since the measure has not been fully specified, tested, or endorsed by the NQF, it may not be thoroughly tested and vetted. They urged CMS, in addition to seeking NQF endorsement, to fully develop and test the measure for reliability and validity before implementing it in the IRF QRP.

Response: Given the novel nature of the SARS–CoV–2 virus, and the significant and immediate health risk it poses in IRFs, we believe it is necessary to propose the measure as soon as possible. Additionally, given the results from CDC's preliminary validity testing of the data elements required for the measure numerator (described further in section VIII.C.1.c. of this final rule), the alignment between the denominator of this measure and the denominator of the Influenza Vaccination among HCP measure (which is NQF-endorsed), and the MAP's determination that the measure has face validity, CMS believes it is appropriate to propose the COVID–19 Vaccination Coverage among HCP measure for the FY 2023 QRP. The CDC, in collaboration with CMS, are planning to submit the measure for consideration in the NQF Fall 2021 measure cycle.

Comment: One commenter expressed concern that the measure was developed for public health tracking during a PHE, not for quality assessment or payment purposes.

Response: This measure was developed for quality assessment purposes. COVID–19 is a contagious respiratory infection[61] that can cause serious illness and death. As of June 25, 2021, the U.S. reported over 33 million cases of COVID–19 and over 600,000 COVID–19 deaths.[62] Immunization has a significant role in reducing the incidence and prevalence—as well as the morbidity and mortality—of vaccine-preventable diseases.[63] Over the past decade, there has been increased focus on improving adult immunization rates. In 2010, the Department of Health & Human Services (HHS) published a National Vaccination Plan which provided a strategic approach for preventing infectious diseases and improving the public's health through vaccination.[64] More recently, a 2014 NQF report emphasized addressing adult immunization measures outside of those addressing influenza and pneumococcal disease and offered recommendations to advance measurement, including a composite of all Advisory Committee on Immunization Practices (ACIP) of the CDC (ACIP/CDC) recommended vaccinations for HCP.[65] The measure was developed in collaboration with the CDC because we believe it is important to require that IRFs report COVID–19 HCP vaccination to assess the potential spread of COVID–19 among their HCP and the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of IRFs to continue serving their communities throughout the PHE and beyond.

Comment: We received a comment asking CMS not to finalize the COVID–19 Vaccination Coverage among HCP measure due to the burden associated with it. The commenter pointed to the reasons previously cited in 2018 for removing the Influenza vaccination measures through NHSN as justification.

Response: We presume the commenter is referring to the removal of the Percent of Residents of Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), which was removed from the IRF QRP in the FY 2019 IRF PPS final rule (83 FR 38559 to 38560). The reason the measure was removed was not because of the burden associated with collecting it. We use measure removal factors (§ 412.634(b)(2)) to determine when measures should be removed from the IRF QRP. The Percent of Residents of Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure performance among

[60] Centers for Disease Control and Prevention. Guidance for Unvaccinated People: How to Protect Yourself & Others. June 11, 2021. Available at *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.* Accessed June 24, 2021.

[61] Centers for Disease Control and Prevention. (2021). Symptoms of COVID–19. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.* Accessed June 24, 2021.

[62] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.* Accessed June 24, 2021.

[63] Vaccinate Your Family website. Vaccines are cost saving. Available at *https://vaccinateyourfamily.org/why-vaccinate/vaccine-benefits/costs-of-disease-outbreaks/.* Accessed June 25, 2021.

[64] U.S. Department of Health & Human Services. 2010 National Vaccine Plan. Available at *https://www.hhs.gov/sites/default/files/nvpo/vacc_plan/2010-Plan/nationalvaccineplan.pdf.* Accessed June 25, 2021.

[65] National Quality Forum. Priority Setting for Healthcare Performance Measurement: Addressing Performance Measure Gaps for Adult Immunizations. Available at *https://www.qualityforum.org/Publications/2014/08/Priority_Setting_for_Healthcare_Performance_Measurement_Addressing_Performance_Measure_Gaps_for_Adult_Immunizations.aspx.* Accessed June 25, 2021.

IRFs was so high and unvarying that meaningful distinctions in improvements in performance could no longer be made. Therefore, it met the standard for measure removal Factor 1 (set forth at § 412.634(b)(2)(i)) of the IRF QRP regulations and was removed.

Comment: Several commenters who were concerned about the burden on IRFs stated that the measure would divert resources currently being used to combat the COVID–19 pandemic since their IT systems must be updated to accommodate changes to the IRF QRP. The commenters recommended that CMS delay this measure for at least one full calendar year following the conclusion of the COVID–19 PHE declaration. They believe a delay in adding this new measure to the IRF QRP is needed to avoid imposing an additional burden on IRFs.

Response: We believe it is important to require that IRFs report COVID–19 HCP vaccination as soon as possible to assess the potential spread of COVID–19 among their HCP and the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of IRFs to continue serving their communities throughout the PHE and beyond. Additionally, consistent vaccination reporting by IRFs via the NHSN will help CMS to identify additional resources and tools IRFs may need to address the challenges of the PHE. Accordingly, we do not believe that a delayed reporting effective date is appropriate.

Comment: We received several comments related to the burden of tracking vaccination records. One commenter attributed the burden of reporting the measure to the fact that they keep employee health records outside of their electronic health record (EHR) due to health privacy concerns. Therefore, attempting to identify and collect data on employee vaccine adherence is inherently difficult and burdensome. Another commenter noted the challenges inherent in monitoring and tracking employees who receive multi-dose courses on varying schedules. Still other commenters pointed to the fact that many vaccination sites, including federally run mass vaccination sites, do not communicate with all registries, and that some states do not maintain a registry. We received several comments asking CMS to consider easing the reporting frequency for the COVID–19 Vaccination Coverage among HCP measure. Some commenters stated that reporting vaccinations one week per month rather than one time per quarter is burdensome, while others raise concern that it could cause fluctuations in vaccination rates.

Response: IRFs are currently required to submit data for the Influenza Vaccination among HCP (NQF #0431) measure to the CDC's NHSN Healthcare Personnel Safety Component (HPS) annually. While IRFs will not have the burden of registering and learning how to use the NHSN, we acknowledge there will be burden with collecting the required information. However, we believe it will be minimal because IRFs already have experience successfully reporting information using the NHSN reporting modules. We refer readers to section XIII.C.7. of this final rule for an estimate of burden related to the COVID–19 Vaccination Coverage among HCP measure. The data sources for the number of HCP who have received COVID–19 vaccines may include HCP health records and paper and/or electronic documentation of vaccination given at the healthcare facility, pharmacy, or elsewhere. Further, HCP receiving vaccination elsewhere may provide documentation of vaccination. Additionally, the CDC has provided a number of resources including a tool called the Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel to help IRFs log and track the number of healthcare personnel (HCP) who are vaccinated for COVID–19. IRFs would enter COVID vaccination data for each HCP in the tracking worksheet, and select a reporting week, the data to be entered into the NHSN will automatically be calculated on the Reporting Summary.[66]

Comment: One commenter pointed to the fact that for IRFs within acute care hospitals, separating out which HCP may have had contact with the IRF unit may present a substantial reporting burden while providing little useful information that could not be gleaned from the hospital-wide reports already submitted. Rather than creating an additional reporting requirement applying solely to IRFs, the agency should leverage existing COVID–19 vaccination rate reporting to achieve the agency's goals.

Response: The IRF QRP is a separate reporting program from the Hospital Inpatient Quality Reporting (IQR) Program. Section 1886(b)(3)(B)(viii) of the Act requires subsection (d) hospitals to submit quality measure data to the Secretary. Separately, section 1886(j)(7) of the Act requires the Secretary, among other things, to specify reporting requirements for IRFs. Each distinct Medicare provider reports separately to CMS to meet its reporting obligations for their respective quality programs, as applicable. Because the IRF QRP and the Hospital IQR are separate programs, any HCP who is eligible to work one day during the reporting period in the IRF would be counted for purposes of the IRF QRP COVID–19 Vaccination Coverage among HCP measure, regardless of whether those HCP work in another facility that is also reporting the same measure.

Comment: A few commenters commented on CMS' statement that the COVID–19 Vaccination Coverage among HCP measure was modeled after the Influenza Vaccination among HCP measure. They believe that there are key differences between the two measures, such as how the vaccines are administered and data are collected. They stated that it is common for influenza vaccinations to be administered by the facility itself, whereas COVID–19 vaccination administration has been varied depending on the state and locality the provider is located in. They also point to the fact that the influenza vaccine is administered one time for the entire flu season with a numerator and denominator that can be calculated with relative ease. Another commenter listed the different reporting requirements for the numerator for the COVID–19 vaccination as compared to the influenza vaccination.

Response: We agree that there are key differences between the Influenza Vaccination among HCP measure and the COVID–19 Vaccination Coverage among HCP measure. We acknowledge that even though the CDC modeled the COVID–19 Vaccination Coverage among HCP measure after the Influenza Vaccination among HCP measure, FDA-approved influenza vaccines and the authorized COVID–19 vaccines differ in multiple ways. The reporting requirements for the numerator of the COVID–19 Vaccination Coverage among HCP measure that one commenter listed are due to the fact that some COVID–19 vaccines require two doses to reach full vaccination status, while some COVID–19 vaccines require only one dose. The measures are aligned with respect to the reporting mechanism used to report data (the NHSN) and key components of the measure specifications (for example, the definition of the denominator), but the measures allow for important differences to reflect the reality that the circumstances around vaccine administration (that the commenter points out) are not identical.

[66] Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel at *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.*

Comment: One commenter disagreed with the proposal of adopting the COVID–19 Vaccination Coverage among HCP measure to the IRF QRP, citing the fact that any new measure added to the IRF QRP creates another basis for CMS to financially penalize IRFs for even the smallest infractions of the multitudinous guidance documents concerning not only the reporting of the quality data itself, but the many technical elements required by the CDC's NHSN system for quality data to be processed and transferred to CMS. The commenters stated providers should never be financially penalized if they report all their quality data by the reporting deadlines, but especially when the quality measure concerns an ongoing global pandemic. Other commenters stated that the COVID–19 measure should be outside of the IRF QRP and not be subject to the 2 percent payment penalty or used for payment decisions.

Response: Section 1886(j)(7)(A)(i) of the Act requires the Secretary to apply a 2 percent payment penalty under the IRF QRP to IRFs that fail to meet the IRF QRP reporting requirements during a fiscal year. IRFs that submit IRF QRP data according to the program's requirements during a fiscal year will not receive the 2 percent payment for the fiscal year.

We received comments about the measure in general, but also specific to the numerator and denominator. We address those comments here.

Comment: Several commenters pointed to the fact that providers have many questions about the specifics of the COVID–19 Vaccination Coverage among HCP measure such as what the long-term plans for using the measure in the IRF QRP are. Another commenter believes the measure seemed unnecessary based on the current vaccination push and the fact that due to the Federal Vaccination Schedule, healthcare workers would already have received the vaccination. This commenter did not believe that the measure addressed many of the unknowns still ahead regarding the virus.

Response: We interpret the commenter's reference to the ''Federal Vaccination Schedule'' to be referring to the eligibility criteria during the initial rollout of the COVID–19 vaccine. When the U.S. supply of COVID–19 vaccine was limited, CDC provided recommendations to federal, state, and local governments about who should be vaccinated first. While CDC made recommendations for who should be offered the COVID–19 vaccines first, each state had its own plan. CMS acknowledges that healthcare workers were given priority in receiving the vaccine, but as reported by Medscape Medical News on June 28, 2021,[67] federal data show that one in four hospital workers across the United states are still unvaccinated, and only one in every three hospital workers are vaccinated in the nation's 50 largest health systems. We believe it is critical to measure staff vaccination rates among IRFs even as vaccinations become more common, especially in light of the vaccine hesitancy other commenters have pointed out. As with all measures within the IRF QRP, this measure will be routinely monitored and evaluated, and if substantive changes are necessary, it will be re-specified through the rulemaking process.

In response to the comment questioning the long-term plans for using the measure, as described in sections VIII.C.1.e and VIII.H.2. of this final rule, we proposed to adopt the COVID–19 Vaccination Coverage among HCP measure into the IRF QRP and publicly report on IRF performance. Once a measure is adopted under the IRF QRP, the measure will remain in effect until CMS proposes that it be removed, suspended, or replaced. We refer readers to the CY 2013 Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Payment Systems and Quality Reporting Programs final rule (77 FR 68500 through 68507) for details on this policy.

Comment: One commenter had questions on what ''fully vaccinated'' meant.

Response: The term ''fully vaccinated'' is not used in the proposed COVID–19 Vaccine Coverage among HCP measure. We proposed the numerator for the COVID–19 Vaccination Coverage among HCP measure to include a complete vaccination course as defined in section VIII.C.1.e of this final rule. We refer the commenter to the CDC's website at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html* where the term ''fully vaccinated'' is defined.

Comment: One commenter requested that once the pandemic subsided, that CMS restructure the reporting of this measure to be more similar to the influenza measure.

Response: The Influenza Vaccination among HCP (NQF #0431) measure reports the percentage of HCP who receive the influenza vaccination during the time from October 1 (or when the vaccine is available) through March 31 of the following year,[68] and is reported annually. CMS will continually monitor and evaluate this measure to ensure it remains clinically valid. If substantive revisions are needed in the future, such revisions would be proposed through the notice and comment rulemaking process.

Comment: Commenters pointed out that the Influenza Vaccination among HCP (NQF #0431) measure utilizes providers working in the facility for the denominator, whereas the proposed COVID–19 metric utilizes providers eligible to work in the facility. Several commenters requested that CMS revise the denominator to include eligible providers who have worked at the facility during the period being measured, similar to the influenza measure. They believe this would be important due to differences across states as to whom would be considered ''eligible'' to work due to laws such as the Family Medical Leave Act (FMLA) and state-level laws associated with defining employee status.

Response: The COVID–19 Vaccination Coverage among HCP measure includes in its calculation HCP who work regularly in an IRF. At times HCP who work in a facility may be temporarily absent from the facility for any reason including illness, injury, vacation, or leave. The Influenza Vaccination among HCP measurement period is the entire 6-month influenza season so such temporary absences will not affect the influenza measure denominator. However, the COVID–19 vaccination Coverage among HCP measure has a measurement period of only 1 week, which is shorter than the timeframe covered by the influenza vaccination measure. This difference accounts for a HCP who works at an IRF who may be absent during this shortened period. Therefore, HCP who work in the IRF, but may be temporarily absent from the facility for up to 2 weeks, are still to be included in the measure denominator.[69]

Comment: Several providers and provider organizations sent in comments about the vaccine's contraindications. Several commenters

[67] Medscape. Disturbing Number of Hospital Workers Still Unvaccinated. Available at *https://www.medscape.com/viewarticle/953871*. Accessed July 13, 2021.

[68] National Quality Forum. Influenza Vaccination Coverage among Healthcare Personnel. Available at *https://qualityforum.org/QPS/QPSTool.aspx?Exact=fase&Keyword=0431#*. Accessed June 26, 2021.

[69] National Healthcare Safety Network. Instructions for Completion of the Weekly Healthcare Personnel COVID–19 Cumulative Vaccination Summary Form for Non-Long-Term Care Facilities (57.220, Rev 3). Available at *https://www.cdc.gov/nhsn/forms/instr/57.220-toi-508.pdf*. Accessed June 26, 2021.

stated that contraindications are poorly defined, continue to change, and vary depending on the vaccine administered. They point out that misinterpretation could lead to fluctuations in the denominator. They acknowledge that CDC has narrowed the list of contraindications, but ''precautions'' still exist, and they are uncertain how precautions should be taken into account for reporting purposes.

Response: Since authorized for emergency use by the FDA, over 300 million doses of the COVID–19 vaccine have been administered in the United States.[70] These vaccines have undergone the most intensive safety monitoring for a vaccine in U.S. history.[71] This monitoring includes using both established and new safety monitoring systems to make sure that COVID–19 vaccines are safe. Contraindications are listed in the FDA patient and provider Fact Sheets and in the Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United States at *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.* Information may be updated based on data from safety monitoring systems at any time. Contraindications and other clinical considerations, while rare, are accounted for in the COVID–19 Vaccination Coverage among HCP measure. However, the precautions listed should not be reported as contraindications, as these are not measure exclusions.

Comment: One commenter questioned whether immunization sites are currently capturing all immunization activity, which could lead to lapses in and inaccurate reporting.

Response: We are unclear what issue the commenter is referring to and how it impacts the proposal to adopt the COVID–19 Vaccination Coverage among HCP measure into the IRF QRP. The data sources for the number of HCP who have received COVID–19 vaccines may include HCP health records and paper and/or electronic documentation of vaccination given at the healthcare facility, pharmacy, or elsewhere. HCP receiving vaccination elsewhere should provide documentation of vaccination.[72]

Comment: Several commenters shared their opinion that refining the measure and timeline would be appropriate before full implementation. They stated that adopting the measure into the QRP should hinge upon full approval by the FDA across all existing submitted vaccines under the EUA. They stated that feedback from the field is needed to ensure that the measure reflects the most current knowledge and evidence. They stated that there is still much unknown regarding the long-term effectiveness of the current COVID–19 vaccine under the EUA, and whether there will be the need for periodic re-inoculation to maintain immunity. They urged CMS to remain flexible on the proposed measure and adjust it accordingly based on the need to revaccinate.

Response: We appreciate that there are unanswered questions related to the SARS-CoV–2 virus and COVID–19 vaccinations. We will routinely monitor and evaluate this measure to ensure it remains valid, reliable, and useful to consumers, and if substantive revisions are needed in the future, such revisions would be proposed through the notice and comment rulemaking process. In the meantime, we believe that the measure specifications as proposed are appropriate, and should be implemented in a manner that provides stakeholders with timely information about staff vaccination rates.

Comment: We received several comments raising concerns that the vaccination rates collected for this measure could vary significantly from the time of data submission to the time they are publicly reported. They believe the time between data submission and reporting will not provide patients with accurate data on the vaccination status of HCP in a specific IRF. They question whether the definition of a fully vaccinated individual could change between the data submission and public reporting of the data, which would provide an even more incomplete window into HCP vaccination rates.

Response: We acknowledge the commenters' concern with regard to timely display of publicly reported data. CMS believes it is important to make the most up-to-date data available to beneficiaries, which will aid them in making essential decisions about health care. In the FY 2016 IRF PPS final rule (80 FR 47126 through 47127), we finalized our procedures for making available to the public information regarding the performance of individual IRFs with respect to the measures required under section 1899B of the Act. The IRF QRP's public display policy allows 4.5 months beyond the end of each calendar year quarter for a number of administrative tasks to occur in sequential order, including allowing sufficient time for IRFs to be able to submit data, review data, make corrections to the data, and view their performance prior to public reporting. Subsequently, a number of administrative tasks must then occur in sequential order between the time IRF QRP data are submitted and they are reported in Care Compare to ensure the validity of the data. We have streamlined the process as much as possible, but must take these steps to ensure we post IRF QRP data accurately. Additionally, the COVID–19 Vaccination Coverage among HCP measure will be one of several measures on Care Compare that patients and caregivers can use to make informed healthcare decisions.

Comment: Several commenters stated that because IRFs would be dependent upon the HCP's permission to allow reporting their vaccination status, it would result in an undercounting of vaccinated HCP for a facility since they could choose not to share this information.

Response: We understand that obtaining information about a person's vaccination status is dependent upon the HCP sharing that information, which is why we encourage providers to voluntarily engage in the provision of appropriate and accessible education and vaccine-offering activities. Many facilities, including IRFs, across the country are educating staff, patients, and patient representatives, and voluntarily reporting vaccine administration. The CDC has a number of resources[73] available to providers to assist in building vaccine confidence. The Department of Health and Human Services (HHS) has launched a national initiative, the ''We Can Do This'' Campaign, to increase public confidence in and uptake of COVID–19 vaccines while reinforcing basic prevention measures such as mask wearing and social distancing. There are a number of resources and toolkits available on the website at *https://wecandothis.hhs.gov/resources,* and the COVID–19 Community Corps is available for communities to participate in to help build vaccine confidence in your

[70] Centers for Disease Control and Prevention. COVID Data Tracker. Available at *https://covid.cdc.gov/covid-data-tracker/#vaccinations.* Accessed June 26, 2021.

[71] Centers for Disease Control and Prevention. Safety of COVID–19 Vaccines. Available at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html.* Accessed June 26, 2021.

[72] National Healthcare Safety Network. Instructions for Completion of the Weekly Healthcare Personnel COVID–19 Cumulative Vaccination Summary Form for Non-Long-Term Care Facilities (57.220, Rev 3). Available at *https://www.cdc.gov/nhsn/forms/instr/57.220-toi-508.pdf.* Accessed June 26, 2021.

[73] Centers for Disease Control and Prevention. Building Confidence in COVID–19 Vaccines. Available at *https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html.* Accessed June 24, 2021.

community. Additionally, the EEOC has guidance [74] that states requesting documentation or other confirmation showing that an employee received a COVID–19 vaccination in the community is not a disability-related inquiry covered by the Americans with Disabilities Act (ADA) and that the federal EEO laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, subject to the reasonable accommodation provisions of Title VII and the ADA.

Comment: A few commenters stated there is no evidence that these measures are reliable, valid, or differentiate between providers. As a result, they have concern that the data informing the measure are not reliable for public consumption. They believe that because of the number of challenges associated with reporting, the data reported are unlikely to be reliable and could therefore unfairly skew a hospital's score on this safety and quality measure.

Response: There is evidence that this measure can identify clinically important differences between providers. As of June 14, 2021, based on reporting to NHSN, there are facilities which reported HCP COVID–19 vaccination coverage rates approaching 100 percent and other facilities which reported HCP COVID–19 vaccination coverage rates below 50 percent (*COVID–19 Nursing Home Data | Data.CMS.gov*). We expect the same level of differentiation to translate to IRFs. This measure was judged to have face validity by the MAP Coordinating Committee, which recognized the unique role that measurement plays in meeting the COVID–19 healthcare crisis through direct measurement of vaccination rates and noted that direct measurement of vaccination for patients and HCP is a key approach to addressing a national healthcare challenge.[75] Additionally, to support the measure's data element validity, CDC conducted testing of the COVID–19 vaccination numerator using data collected through the NHSN and independently reported through the Federal Pharmacy Partnership for Long-term Care Program for delivering vaccines to long-term care facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination, the number of HCP vaccinated in approximately 1,200 facilities, which had data from both systems, was highly correlated between these two systems with a correlation coefficient of nearly 90 percent in the second 2 weeks of reporting.[76] We expect similar validity to translate to IRFs. Finally, we proposed the measure's denominator to use the same identification and categorization as the existing Influenza Vaccination among HCP measure,[77] an NQF-endorsed measure since 2012, which was adopted for the IRF QRP in the FY 2014 IRF PPS final rule (78 FR 47859).

Comment: Two commenters urged CMS to delay adopting the measure until at least a full calendar year following the COVID–19 PHE has ended. They believe the additional time would allow CMS and relevant stakeholders the opportunity to discuss and address the challenges, avoid negative unintended consequences, and ensure the data captured allow accurate reporting that can be trusted by patients and their families. Other commenters recommended that CMS either delay adoption of the measure for at least one year or adopt the measure for voluntary reporting for at least the first year, but any voluntarily reported data should not be publicly reported.

Response: We believe that the unprecedented risks associated with the COVID–19 PHE warrant direct attention. Data show that eight out of every 10 deaths related to COVID–19 have been in adults 65 years of age and older. When compared to 18- to 29-year-olds, adults over 65 have a five to eight times higher risk of being hospitalized from COVID–19 and those older than 75 have a 220 times higher risk of dying.[78] Moreover, many common chronic conditions raise the risks associated with contracting COVID–19, including hypertension, obesity, chronic obstructive pulmonary disease, heart disease, diabetes, and chronic kidney disease.[79]

We believe consistent vaccination reporting by IRFs via the NHSN and public reporting of this information on Care Compare will assist Medicare beneficiaries to make informed choices when selecting IRF care. Further, this measure would facilitate patient care and care coordination during the discharge planning process. A discharging hospital/facility, in collaboration with the patient and family, can use this measure to coordinate care and ensure patient preferences are considered in the discharge plan. Patients at high risk for negative outcomes due to COVID–19 (perhaps due to underlying conditions) can use healthcare provider vaccination rates when they are selecting an IRF for next-level care. While we have taken into consideration comments suggesting that we delay implementation of this measure, we do not believe we can delay monitoring and publicly reporting the COVID–19 Vaccination Coverage among HCP measure. Therefore, we believe it is important to begin publicly reporting this measure as proposed. CMS will routinely monitor and evaluate this measure to identify unintended consequences and to ensure it remains valid, reliable, and useful to consumers. The CDC, in collaboration with CMS are planning to submit the measure for consideration in the NQF Fall 2021 measure cycle.

After careful consideration of the public comments, we are finalizing our proposal to adopt the COVID–19 Vaccination Coverage among HCP measure to the IRF QRP beginning with the FY 2023 IRF QRP.

2. Update to the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure Beginning With the FY 2023 IRF QRP

We proposed to update the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure (TOH-Patient) denominator to exclude patients discharged home under the care of an organized home health service or hospice. This measure assesses for and reports on the timely transfer of health information, specifically transfer of a medication list. We adopted this

[74] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws*. Accessed June 25, 2021.

[75] National Quality Forum. Measure Applications Partnership 2020–2021 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Final Report. March 11, 2021. Available at *http://www.qualityforum.org/Projects/i-m/MAP/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report.aspx*. Accessed June 26, 2021.

[76] Geller, et al. Surveillance of COVID–19 vaccination in US nursing homes, December 2020-April 2021. Medrxiv.org. Available at *https://www.medrxiv.org/content/10.1101/2021.05.14.21257224v1.full.pdf*. Accessed June 26, 2021.

[77] National Quality Forum. Influenza Vaccination Coverage among Healthcare Personnel. Available at *https://qualityforum.org/QPS/QPSTool.aspx?Exact=fase&Keyword=0431#*. Accessed June 26, 2021.

[78] National Institute for Health Care Management (NIHCM). Aging & COVID–19: Vaccination, Mental and Physical Health, and Isolation. Updated February 17, 2021. Available at *https://nihcm.org/publications/aging-covid-19-vaccination-mental-and-physical-health-and-isolation*. Accessed June 26, 2021.

[79] Centers for Disease Control and Prevention. Science Brief: Evidence used to update the list of underlying medical conditions that increase a person's risk of severe illness from COVID–19. Available at *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/underlying-evidence-table.html*. Accessed June 26, 2021.

measure in the FY 2020 IRF PPS final rule (84 FR 39099 through 39107) beginning with the FY 2022 IRF QRP. It is a process-based measure that evaluates for the transfer of information when a patient is discharged from his or her current PAC setting to a private home/apartment, board and care home, assisted living, group home, transitional living, or home under the care of an organized home health service organization or hospice.

This measure, adopted under section 1899B(c)(1)(E) of the Act, was developed to be a standardized measure for the IRF QRP, LTCH QRP, SNF QRP, and Home Health (HH) QRP. The measure is calculated by one standardized data element that asks, ''At the time of discharge, did the facility provide the patient's current reconciled medication list to the patient, family, and/or caregiver?'' The discharge location is captured by items on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI).

Specifically, we proposed to update the measure denominator. Currently the measure denominators for both the TOH-Patient and the TOH-Provider measure assess the number of patients discharged home under the care of an organized home health service organization or hospice. In order to align the measure with the SNF QRP, LTCH QRP, and HH QRP and avoid counting the patient in both TOH measures in the IRF QRP, we proposed to remove this location from the definition of the denominator for the TOH-Patient measure. Therefore, we proposed to update the denominator for the TOH-Patient measure to only discharges to a private home/apartment, board and care home, assisted living, group home, or transitional living. For additional technical information regarding the TOH-Patient measure, we refer readers to the document titled ''Final Specifications for IRF QRP Quality Measures and Standardized Patient Assessment Data Elements (SPADEs)'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/Final-Specifications-for-IRF-QRP-Quality-Measures-and-SPADEs.pdf.*

We invited public comment on our proposal to update the denominator of the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure beginning with the FY 2023 IRF QRP.

The following is a summary of the public comments received on our proposal to update the denominator of the TOH-Patient measure beginning with the FY 2023 IRF QRP and our responses:

Comment: We received overwhelming support for our proposal to update the TOH-Patient measure's denominator to remove the inclusion of ''home under care of an organized home health service organization or hospice.'' Commenters agreed that the update will further improve the validity and usefulness of the measure, while reducing provider burden. Some commenters stated that while they recognize the burden the PHE has had on all healthcare facility types, an accurate medication list is important to continuity of care. One commenter urged CMS to seek endorsement from the NQF on this measure, since it is not currently endorsed for use in PAC settings, including IRFs.

Response: We appreciate the commenter's support. We plan to submit the measure for NQF endorsement.

Comment: One provider noted disappointment that the measure has been delayed for at ''least two full fiscal years after the end of the PHE.''

Response: We refer the commenter to the CY 2022 HH PPS proposed rule (86 FR 35874) where we proposed to revise the compliance date for the collection of data on the Transfer of Health Information to Provider-PAC measure and Transfer of Health Information to Patient-PAC measure and certain Standardized Patient Assessment Data Elements under the IRF QRP beginning October 1, 2022 and invite public comment on the proposal.

After careful consideration of the public comments, we are finalizing our proposal to update the denominator of the Transfer of Health (TOH) Information to the Patient—Post Acute Care (PAC) measure beginning with the FY 2023 IRF QRP.

D. IRF QRP Quality Measures Under Consideration for Future Years: Request for Information

We solicited input on the importance, relevance, appropriateness, and applicability of each of the measures and concepts under consideration listed in Table 9 for future years in the IRF QRP.

TABLE 9: Future Measures and Measure Concepts Under Consideration for the IRF QRP

Assessment-Based Quality Measures and Measure Concepts
Frailty
Opioid use and frequency
Patient reported outcomes
Shared decision making process
Appropriate pain assessment and pain management processes
Health equity

We received several comments on this RFI, which are summarized below:

Comment: Several commenters supported the inclusion of all the proposed measures listed in Table 9. One commenter stated that all of the measures and measure concepts are important and relevant for assessing quality of care delivered to IRF patients. Another commenter stated that the concepts should generate valuable data points to consider.

Many commenters supported the concept of frailty, and one commenter stated they are encouraged to see frailty included since a frailty diagnosis can be linked to a risk for falls and subsequent adverse clinical events. Several commenters, however, did not recommend a measure of frailty be included in the IRF QRP. Another commenter thought that the term ''frailty'' is non-specific and is a concept that may not be well understood or applied.

Many commenters supported the measure concept of the shared decision-making process while others questioned how it could be captured in the IRF QRP. One commenter stated that while shared decision-making is a very important component of patient-

centered care, IRFs are unique settings that are not well-suited for inclusion in certain shared decision-making performance measures since shared decision-making requires that multiple options of the same clinical value be presented to the patient. Other commenters stated that since informed decision making is already part of the CMS Conditions of Participation (CoP), this would likely not add any value to providers or patients, and they do not support adding what they believe would likely be another process measure.

Several commenters supported the concept of patient-reported outcomes (PROs). One commenter stressed the importance of PROs since they determine outcomes based on information obtained directly from patients, and therefore provide greater insight into patients' experience of the outcomes of care. Some commenters did not support the concept of PROs because they believe many patients treated in the IRF are unable to verbalize and/or lack the cognitive capacity to accurately express themselves.

Several commenters were supportive of the inclusion of pain management quality measures, while others were concerned about the reporting of opioid use and frequency as a quality measure due to the potential for over- or under-prescribing of opioids. One commenter stated that because pain is often an inherent part of intensive rehabilitation therapy, and is already frequently assessed, it is not an appropriate quality reporting measure for the IRF QRP. Several commenters stated that a more meaningful pain measure in the IRF setting would be designed to assess whether staff are responsive to and help manage patients' pain.

Commenters were generally supportive of the concept of health equity in quality measurement. They agree that closing the health equity gap is essential to ensure optimal health services and outcomes to all Americans regardless of individual characteristics.

A couple of commenters encouraged CMS to remove topped-out measures and low-occurrence measures to ensure the IRF QRP remains relevant to quality and performance, and another commenter suggested removal of two of the IRF QRP measures currently reported. Finally, one commenter did not support any additional measures or measure concepts due to the burden associated with adding measures to the IRF QRP.

Commenters also suggested other concepts for quality measurement in the IRF QRP such as quality of life, mental health, and nutritional status.

Response: We appreciate the input provided by commenters. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this input to inform our future measure development efforts.

E. Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Quality Programs—Request for Information

1. Solicitation of Comments

We sought input on the following steps that would enable transformation of CMS' quality measurement enterprise to be fully digital:

- What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?
- How do you currently share information with other providers?
- In what ways could we incentivize or reward innovative uses of health information technology (IT) that could reduce burden for post-acute care settings, including but not limited to IRFs?
- What additional resources or tools would post-acute care settings, including but not limited to IRFs, and health IT vendors find helpful to support the testing, implementation, collection, and reporting of all measures using FHIR standards via secure APIs to reinforce the sharing of patient health information between care settings?
- Would vendors, including those that service post-acute care settings, such as IRFs, be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would align standards for quality measure data collection across care settings to improve care coordination, such as sharing patient data via secure FHIR API as the basis for calculating and reporting digital measures?

We received a number of comments and appreciate the time commenters took to respond. We plan to continue working with other agencies and stakeholders to coordinate and to inform our transformation to dQMs leveraging health IT standards. We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

F. Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs—Request for Information

1. Solicitation of Public Comment

Under authority of the IMPACT Act and section 1886(j)(7) of the Act, we sought comment on the possibility of revising measure development, and the collection of other SPADEs that address gaps in health equity in the IRF QRP. Any potential health equity data collection or measure reporting within a CMS program that might result from public comments received in response to this solicitation would be addressed through a separate notice-and-comment rulemaking in the future.

Specifically, we invited public comment on the following:

- Recommendations for quality measures or measurement domains that address health equity, for use in the IRF QRP.
- As finalized in the FY 2020 IRF PPS Final Rule (84 FR 39149 through 39161), IRFs must report certain standardized patient assessment data (SPADEs) on SDOH, including race, ethnicity, preferred language, interpreter services, health literacy, transportation and social isolation.[80] CMS is seeking guidance on any additional items, including SPADEs that could be used to assess health equity in the care of IRF patients, for use in the IRF QRP.
- Recommendations for how CMS can promote health equity in outcomes among IRF patients. For example, we are interested in feedback regarding whether including facility-level quality measure results stratified by social risk factors and social determinants of health (for example, dual eligibility for Medicare and Medicaid, race) in confidential feedback reports could allow facilities to identify gaps in the quality of care they provide. (For example, methods similar or analogous to the CMS Disparity Methods[81] which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures which are currently included in the Hospital Readmission Reduction Program (see 84 FR 42496 through 42500)).
- Methods that commenters or their organizations use in employing data to reduce disparities and improve patient outcomes, including the source(s) of data used, as appropriate.

[80] In response to the COVID–19 PHE, CMS released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the SDOH for at least one full fiscal year after the end of the PHE.

[81] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

• Given the importance of structured data and health IT standards for the capture, use, and exchange of relevant health data for improving health equity, the existing challenges providers encounter for effective capture, use, and exchange of health information, such as data on race, ethnicity, and other social determinants of health, to support care delivery and decision making.

While we will not be responding to specific comments submitted in response to this Health Equity RFI in this final rule, we appreciate all of the comments and interest in this topic. We will continue to take all concerns, comments, and suggestions into account as we continue work to address and develop policies on this important topic. It is our hope to provide additional stratified information to providers related to race and ethnicity if feasible. The provision of stratified measure results will allow IRFs to understand how they are performing with respect to certain patient risk groups, to support these providers in their efforts to ensure equity for all of their patients and to identify opportunities for improvements in health outcomes.

G. Form, Manner, and Timing of Data Submission Under the IRF QRP

1. Background

We refer readers to the regulatory text at 42 CFR 412.634(b) for information regarding the current policies for reporting IRF QRP data.

2. Schedule for Data Submission of the COVID–19 Vaccination Coverage Among Healthcare Personnel Measure Beginning With the FY 2023 IRF QRP

As discussed in section VII.C.1 of the proposed rule, we proposed to adopt the COVID–19 Vaccination Coverage among HCP measure beginning with the FY 2023 IRF QRP. Given the time-sensitive nature of this measure in light of the PHE, we proposed an initial data submission period from October 1, 2021 through December 31, 2021. Starting in CY 2022, IRFs would be required to submit data for the entire calendar year beginning with the FY 2024 IRF QRP.

IRFs would submit data for the measure through the CDC/NHSN web-based surveillance system. IRFs currently utilize the NHSN for purposes of meeting other IRF QRP requirements.[82] IRFs would use the COVID–19 vaccination data reporting module in the NHSN Healthcare Personnel Safety (HPS) Component to report the cumulative number of HCP eligible to work in the healthcare facility for at least 1 day during the reporting period, excluding persons with contraindications to COVID–19 vaccination (denominator) and the cumulative number of HCP eligible to work in the IRF for at least 1 day during the reporting period and who received a complete vaccination course against COVID–19 (numerator). IRFs would submit COVID–19 vaccination data through the NHSN for at least 1 week each month and the CDC would report to CMS quarterly.

We invited public comment on this proposal.

The following is a summary of the public comments received on the proposed revisions to the Form, Manner, and Timing of Data Submission under the IRF QRP and our responses:

Comment: A number of commenters wrote to CMS about the administrative burden associated with reporting of the measure through NHSN. They pointed to other reporting systems being used around the country and stated that this would be duplicative reporting. Several commenters referenced the Department of Health and Human Services TeleTracking system, VaccineFinder, and various state agencies and databases. They stated that having to utilize these systems with different reporting periods in addition to the NHSN and its reporting period utilizes additional resources and will require multiple tracking strategies to keep up. They urged CMS to use data from these systems without requiring additional data collection in the NHSN. Several of these commenters requested that if the measure is finalized, that CMS utilize the data submitted through the TeleTracking system.

Response: The TeleTracking system was one system that was used to manage the critical first months of the COVID–19 PHE, as it was critical that the federal government received data to facilitate planning, monitoring, and resource allocation during the PHE for COVID–19. The TeleTracking system collects a number of data points, such as ventilators in the facility, ventilators in use, ICU beds available, and ICU beds occupied. However, the TeleTracking system was not used for the IRF QRP. We have proposed to use the NHSN COVID–19 Modules for tracking COVID–19 Vaccination Coverage among HCP across all sites of service, including IRFs, as most of the state Immunization Information Systems do not include the information needed to calculate the COVID–19 Vaccination Coverage among HCP.

For meeting the requirements of the IRF QRP, we do not prescribe which day of the week the data for the COVID–19 vaccinations must be submitted. We refer readers to section VIII.G.2 describing the proposal for data submission to the NHSN for more detail.

Comment: Another commenter encouraged CMS to evaluate both methods of how data are submitted (that is, the TeleTracking system and the NHSN) and select just one standardized data reporting system and process. This commenter was in favor of using the NHSN to report the COVID–19 Vaccination Coverage among HCP measure because all care settings are using it to report the Influenza Vaccination Coverage among HCP and discontinuing COVID–19 vaccination reporting to the HHS tracking system. Another commenter urged CMS to use the TeleTracking system since the data fields collected in it are less detailed than what is required in the NHSN.

Response: We proposed to use the NHSN COVID–19 Modules for tracking COVID–19 Vaccination Coverage among HCP across all sites of service, including IRFs. IRFs are familiar with NHSN since they use it to submit information for other CDC measures and this system facilitates calculation of the COVID–19 Vaccination Coverage among HCP measure so CMS can meet its public reporting obligations to provide information to beneficiaries seeking care from IRFs.

Comment: One commenter stated that the reporting burden would be high depending on how reporting for the COVID–19 Vaccination Coverage among HCP measure interacts with other COVID–19 data reporting requirements, and adding this measure would require adjustments in workflow for which CMS would need to provide significant technical support.

Response: IRFs are currently required to submit data for the Influenza Vaccination among HCP measure (NQF #0431) to the CDC's NHSN Healthcare Personnel Safety Component (HPS) annually. Therefore, we believe the burden for adding the COVID–19 Vaccination Coverage among HCP measure will be minimal for IRFs, since IRFs already have experience successfully reporting information using the NHSN reporting modules.

Comment: We received several comments requesting that CMS consider reducing the reporting frequency for the COVID–19 Vaccination Coverage among HCP measure. They stated that reporting COVID–19 vaccinations 1 week per month, rather than one time per quarter

[82] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

is burdensome. They recommended CMS use quarterly reporting periods to align with the influenza vaccination reporting schedule.

Response: The COVID–19 Vaccination Coverage among HCP measure measurement period is only 1 week, considerably shorter than the time period covered by the Influenza Vaccination among HCP measure (NQF #0431). Additionally, the reporting schedule of 1 week per month was chosen to provide vaccination coverage data on a more timely basis than the Influenza Vaccination among HCP measure (NQF #0431), while also reducing the burden on IRFs that weekly reporting of this information would have been.

Comment: A couple of commenters were concerned that allowing IRFs to select which week of the month they will report could lead to IRFs selecting the week in which the highest number of employees completed a vaccination course. They were also concerned about having only 1 week out of the month represent a full month because it might add a confounding variable to the data and potentially reduce the value to healthcare consumers.

Response: We proposed to allow IRFs to select which week of the month to report for additional flexibility. We note that counts reported during a given week should reflect the cumulative number of eligible HCP (as defined in the COVID–19 Vaccination Coverage among HCP measure specifications [83]) during the reporting period. Thus, IRFs have the flexibility to select a week that they determine is sufficiently representative of the month. The amount of burden reduction by reporting 1 week a month vs. every week a month is expected to outweigh any confounding variable that the commenters may be referring to. While the reporting experience during the PHE may not reflect the experience after the PHE, it is not expected the week -to -week variation will significantly change vaccination coverage rates, particularly as the denominator of HCP consists of those who regularly work in the facility, including HCP who may be on temporary (less than 2-week) leave.

Comment: A few commenters were concerned about having a shortened reporting period of October 1, 2021 through December 31, 2021 to assess reporting requirements for the FY 2023 IRF QRP.

Response: In the FY 2016 IRF PPS Final Rule (80 FR 47122 to 47123), CMS revised the data collection time frame for the IRF QRP to a calendar year, unless there is a clinical reason for an alternative data collection time frame.[84] We believe this simplifies the data collection and submission time frame under the IRF QRP for IRFs, and also eliminates the situation in which data collection during a quarter in the same calendar year can affect two different years of annual payment update determination.[85] Therefore this proposed data collection and submission time frame is consistent with the IRF QRP, and we are confident in IRFs' ability to meet the reporting period since they have demonstrated their ability to do so since FY 2016.

Comment: A couple of commenters are also concerned about having different reporting timelines for the COVID–19 Vaccination Coverage among HCP measure and the Influenza Vaccination among HCP measure (NQF #0431). They raised the question of whether providers would only have 6 weeks after the end of the quarter to submit data for the COVID–19 Vaccination Coverage among HCP measure, since this is the deadline for the Influenza Vaccination among HCP measure (NQF #0431). Some commenters recommended that CMS use the reporting deadlines used for the influenza measures, while others recommended CMS set the deadline for reporting the proposed COVID–19 Vaccination Coverage among HCP measure data consistent with existing NHSN requirements.

Response: We thank the commenter for the question. While both measures assess vaccination rates among HCP, they are operationalized differently. The shortened deadline for the Influenza Vaccination among HCP measure (NQF #0431) is necessary to make the data available in the public reporting cycle more timely. Since the influenza vaccination season ends March 31, a 6-week reporting period is necessary in order to publish the measure in the next available public reporting refresh. Because the transmission of SARS-CoV–2 virus currently has no established seasonality, we proposed 4.5 months after the end of the quarter for IRFs to report the data. Additionally, since the measure will not be publicly reported until the Fall of 2022, we are able to allow the standard review and correct time periods.

Comment: One commenter stated that since the measure requires COVID–19 vaccination rates to be reported monthly, using 1 week of data, it would mean that reporting IRFs will need to recalculate the numerator and denominator every reporting period in order to submit an accurate report. They stated it would require outreach to all employees, and a weekly review of the employee roster to ensure ongoing accuracy, since the number could potentially change daily.

Response: IRFs do not need to recalculate the numerator and denominator every reporting period. IRFs complete the weekly COVID–19 cumulative vaccination counts among HCP using the NHSN module, and the CDC reports the data to CMS quarterly.

After careful consideration of the public comments, we are finalizing our proposal to require IRFs to submit COVID–19 Vaccination Coverage among HCP measure data through the NHSN for at least 1 week each month for the CDC to report to CMS quarterly.

H. Policies Regarding Public Display of Measure Data for the IRF QRP

1. Background

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF QRP data available to the public after ensuring that IRFs have the opportunity to review their data prior to public display. IRF QRP measure data are currently displayed on the *Inpatient Rehabilitation Facilities* website within Care Compare and the Provider Data Catalog. Both Care Compare and the Provider Data Catalog replaced IRF Compare and *Data.Medicare.gov*, which were both retired in December 2020. For a more detailed discussion about our policies regarding public display of IRF QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 IRF PPS final rule (81 FR 52125 through 52131).

2. Public Reporting of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2023 IRF QRP

We proposed to publicly report the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the September 2022 Care Compare refresh or as soon as technically feasible based on data

[83] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage Updated March 2021. Available at *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.* Accessed June 27, 2021.

[84] The NHSN Influenza Vaccination among HCP measure's (NQF #0431) data collection period is tied to the influenza vaccination season.

[85] We refer readers to Section IX.H.3. of the FY 2016 IRF PPS Final Rule (80 FR 47122 to 47123). Available at *https://www.federalregister.gov/documents/2015/08/06/2015-18973/medicare-program-inpatient-rehabilitation-facility-prospective-payment-system-for-federal-fiscal.* Accessed June 26, 2021.

collected for Q4 2021 (October 1, 2021 through December 31, 2021). If finalized as proposed, an IRF's HCP COVID–19 vaccination coverage rates would be displayed based on one quarter of data updated quarterly. Subsequent to this, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four full quarters of data is reached. Thereafter, the measure would be reported using four rolling quarters of data.

We invited public comment on the proposal for the public display of the measure, COVID–19 Vaccination Coverage among HCP.

The following is a summary of the public comments received on our proposal for the public display of the measure, COVID–19 Vaccination Coverage among HCP and our responses:

Comment: One commenter voiced concern that it was premature to publicly report this measure at this time due the fact the measure would need to be reported for several years and the underlying evidence needed time to become more stable. Another commenter stated that the measure is not mature enough for use in a payment program at this time, and questions the value this outdated, and potentially incomplete information would bring in FY 2023.

Response: The global outbreak of SARS-CoV–2, which resulted in the declaration of a PHE, took a significant toll on institutionalized patients, including those in IRFs, who are often at higher risk for more serious complications from the virus. We acknowledge that the science relating to SARS-CoV–2 virus is continuing to evolve, and we are still learning how effective the vaccines are against new variants of the virus that causes COVID–19. However, current information suggests that COVID–19 vaccines authorized for use in the United States offer protection against most variants in the United States.[86]

Furthermore, we do not believe that the public reporting of this information should be delayed because patients should have access to vaccination information when selecting an IRF in which they will receive care. CMS will be actively monitoring this measure and the evolving circumstances around the PHE. If substantive revisions to this measure are needed in the future, such revisions would be proposed through the notice and comment rulemaking process at that time.

Comment: Several commenters stated that if CMS adopted the COVID–19 Vaccination Coverage among HCP measure, then the data will be publicly displayed on Care Compare without proper context. They are concerned the public will not understand the legal issues providers feel pressured and/or constrained by, nor the information concerning FDA approval.

Response: The comments concerning legal risks are vague and we are not clear about the legal risks that commenters are referring to. Commenters have raised these concerns related to the vaccine's FDA approval and the inability to require their HCP to receive a COVID–19 vaccination. The COVID–19 vaccinations received Emergency Use Authorization (EUA) by the FDA. We refer readers to the FDA website for additional information related to the process of vaccination vetting and approval at *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.* The EEOC released updated and expanded technical assistance on May 28, 2021.[87] Specifically the EEOC stated the federal equal employment opportunity (EEO) laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEO considerations.

Comment: Several commenters questioned whether the COVID–19 Vaccination Coverage among HCP measure data will be of value in 2023 and beyond given the time associated with data collection, submission, and validation. While they support the rights of consumers to access real-time meaningful data to help inform healthcare decision-making, they believe that the use of a single, dated measure is not a true reflection of the safety or quality of care delivered at the IRF.

Response: We proposed the COVID–19 Vaccination Coverage among HCP measure be reported beginning with the September 2022 Care Compare refresh or as soon as technically feasible, rather than 2023. However, we acknowledge the commenters' concern with regard to timely display of publicly reported data. We believe it is important to make the most up-to-date data available to beneficiaries, which will support them in making essential decisions about health care. Based on these concerns, we believe it is appropriate to revise the measure's public reporting policy to use quarterly reporting, as opposed to averaging over four rolling quarters, which would allow the most recent quarter data to be displayed without combining it with older quarters of data. This revision would not affect the data collection schedule we proposed for submitting data to NHSN for the COVID–19 vaccination Coverage among HCP measure. This revision would simply update the way the measure's data are displayed for public reporting purposes. As always, IRFs will be given the chance to preview their COVID–19 Vaccination Coverage among HCP measure score, prior to the public posting of these data.

CMS will closely monitor this measure over the next year, and consider any adjustments that are needed with respect to the status of and the circumstances surrounding the PHE at that time. If substantive revisions are needed in the future, such revisions would be proposed through the notice and comment rulemaking process. Additionally, reporting of a new or revised measure would be addressed at the time of the notice and comment rulemaking process.

Comment: Commenters had different opinions on whether the information obtained from the COVID–19 Vaccination Coverage among HCP measure would be helpful to consumers. Some stated that it does little to guide patients and their caregivers in the discharge planning process or to distinguish IRFs from one another. Another commenter acknowledged the value of this information for public health and educational purposes, but still believes it would not be appropriate at this time to report publicly on the COVID–19 Vaccination Coverage among HCP measure for the purposes of assessing IRF quality performance.

Response: We believe remaining COVID–19- free while receiving IRF care is critically important for Medicare beneficiaries, and therefore would be helpful to consumers. We regularly perform consumer testing on measures that are available on Care Compare to ensure that Care Compare supports patients and caregivers in making

[86] Centers for Disease Control and Prevention. Covid-19 vaccines and new variants. Available at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/work.html#:~:text=COVID%2D19%20vaccines%20and%20new%20variants%20of%20the%20virus&text=Current%20data%20suggest%20that%20COVID,after%20they%20are%20fully%20vaccinated.* Accessed June 25, 2021.

[87] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.* Accessed June 25, 2021.

informed choices about critical dimensions of quality. Public reporting of this measure will inform patients and caregivers on IRFs' response to the PHE.

We also disagree that the measure does little to guide the discharge planning process, but rather this measure would facilitate patient care and care coordination during the discharge planning process. A discharging hospital/facility, in collaboration with the patient and family, can use this measure to coordinate care and ensure patient preferences are considered in the discharge plan. Patients at high risk for negative outcomes due to COVID–19 (perhaps due to underlying conditions) can use healthcare provider vaccination rates when they are selecting an IRF for next-level care.

After careful consideration of the public comments, we are finalizing our proposal to publicly report the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the September 2022 Care Compare refresh or as soon as technically feasible based on data collected for Q4 2021 (October 1, 2021 through December 31, 2021) with the modification that we will not finalize our plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. We will instead only report the most recent quarter of data.

3. Public Reporting of Quality Measures in the IRF QRP With Fewer Quarters Due to COVID–19 Public Health Emergency (PHE) Exemptions

a. COVID–19 Public Health Emergency Temporary Exemptions

Under the authority of section 319 of the Public Health Service Act, the Secretary of Health and Human Services declared a public health emergency (PHE) effective as of January 27, 2020. On March 13, 2020, subsequent to a presidential declaration of national emergency under the Stafford Act, the Secretary invoked section 1135(b) of the Act (42 U.S.C. 1320b-5) to waive or modify the requirements of titles XVIII, XIX, and XXI of the Act and regulations related to the PHE for COVID–19, effective as of March 1, 2020.[88] On March 27, 2020, we sent a guidance memorandum under the subject title, ''Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19'' to the Medicare Learning Network (MLN) Connects Newsletter and Other Program-Specific Listserv Recipients,[89] hereafter referred to as the March 27, 2020 CMS Guidance Memo. In that memo we granted an exception to the IRF QRP reporting requirements from Q4 2019 (October 1, 2019–December 31, 2019), Q1 2020 (January 1, 2020–March 31, 2020), and Q2 2020 (April 1, 2020–June 30, 2020). We also stated that we would not publicly report any IRF QRP data that might be greatly impacted by the exceptions from Q1 and Q2 of 2020. This exception impacted the schedule for public reporting that would have included those two quarters of data.

IRF quality measures are publicly reported on Care Compare. Care Compare uses four quarters of data for IRF–PAI assessment-based measures and eight quarters for claims-based measures. Table 10 displays the original schedule for public reporting of IRF QRP measures.[90]

[88] *https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.*

[89] *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

[90] More information about the IRF QRP Public Reporting schedule can be found on the IRF QRP Public Reporting website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Public-Reporting.*

TABLE 10: IRF Quarters in Care Compare Original Schedule for Refreshes Affected by COVID-19 PHE Exemptions - Assessment and Claims Based Measures

Quarter Refresh	IRF Quarters in Original Schedule for Care Compare
Actual December 2020 (on Care Compare)	IRF-PAI: Q1 2019 – Q4 2019 (4 quarters)* Claims: Q4 2017 – Q3 2019 (8 quarters)
Original December 2020	IRF-PAI: Q2 2019 – Q1 2020 (4 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
March 2021	IRF-PAI: Q3 2019 – Q2 2020 (4 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
June 2021	IRF-PAI: Q4 2019 – Q3 2020 (4 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
September 2021	IRF-PAI: Q1 2020 – Q4 2020 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
December 2021	IRF-PAI: Q2 2020 – Q1 2021 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
March 2022	IRF-PAI: Q3 2020 – Q2 2021 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
June 2022	IRF-PAI: Q4 2020 – Q3 2021 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
September 2022	IRF-PAI: Q1 2021 – Q4 2021 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
December 2022	IRF-PAI: Q2 2021 – Q1 2022 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
March 2023	IRF-PAI: Q3 2021 – Q2 2022 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
June 2023	IRF-PAI: Q4 2021 – Q3 2022 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)

* The September 2020 refresh was postponed to December 2020 for technical reasons. The period of performance listed here reflects the data that was originally scheduled to be used to calculate provider performance for the December 2020 refresh.

During 2020, we conducted testing to inform decisions about publicly reporting data for those refreshes, which include partially and/or fully exempt data (discussed below). The testing helped us develop a plan for posting data that are as up-to-date as possible and that also meet acceptable standards for public reporting. We believe that the plan allows us to provide consumers with helpful information on the quality of IRF care, while also making the necessary adjustments to accommodate the exemption provided IRFs. The following sections provide the results of our testing, and explains how we used the results to develop plans for accommodating exempt and partially-exempt data in public reporting.

b. Exempted Quarters

In the March 27, 2020, Medicare Learning Network (MLN) Newsletter on Exceptions and Extensions for Quality Reporting Program (QRP) Requirements, we stated that we would not report any PAC quality data that might be greatly impacted by the exemptions granted for Quarter 1 and Quarter 2 of 2020. Given the timing of the PHE onset, we determined that we would not use IRF–PAI assessments or IRF claims from Quarter 1 and Quarter 2 of 2020 for public reporting, but that we would assess the COVID–19 PHE impact on data from Quarter 4 2019. Before proceeding with the December 2020 refresh, we conducted testing to ensure that, despite the voluntary nature of reporting for that quarter, public reporting would still meet our public reporting standards. We found the level of reporting, measured in the number of eligible stays and providers, and the reported outcomes, to be in line with levels and trends observed in FY 2018 and FY 2019. We note that Quarter 4 2019 ended before the onset of the COVID–19 pandemic in the United States. Thus, we proceeded with including these data in IRF QRP measure calculations for the December 2020 refresh.

c. Update on Data Freeze and Proposal for December 2021 Public Reporting Methodology for IRF Claims-Based and IRF–PAI Assessment-Based Measures

In addition to the March 2021 refresh, there are several other forthcoming refreshes for which the original public reporting schedules included exempted quarters of IRF QRP data. The impacted refreshes for IRF–PAI assessment and claims based measures are outlined above (Table 10). We determined that freezing the data displayed on the website with the December 2020 refresh values—that is, hold data constant after the December 2020 refresh data on the website without subsequent update—would be the most straightforward, efficient, and equitable approach for IRFs. Thus, we decided that, for as many refreshes as necessary, we would hold data constant on the website with the December 2020 data, and communicate this decision to the public.

Because December 2020 refresh data will become increasingly out-of-date and thus less useful for consumers, we

analyzed whether it would be possible to use fewer quarters of data for one or more refreshes and thus reduce the number of refreshes that continue to display December 2020 data. Using fewer quarters of more up-to-date data requires that: (1) A sufficient percentage of IRFs would still likely have enough assessment data to report quality measures (reportability); and (2) fewer quarters would likely produce similar measure scores for providers, with similar reliability, and thus not unfairly represent the quality of care IRFs provide during the period reported in a given refresh (reliability).

To assess these criteria, we conducted reportability and reliability analysis using 3 quarters of data in a refresh, instead of the standard 4 quarters of data for reporting assessment-based measures and using 6 quarters instead of 8 for claims-based measures. Specifically, we used historical data to calculate IRF–PAI assessment-based and IRF claims-based measures under two scenarios:

(1) *Standard Public Reporting (SPR) Base Scenario:* We used four quarters of CY 2019 data as a proxy alternative for the exempted quarters in CY 2020 in order to compare results. For assessment-based measures, the quarters used in this scenario are Q1 through Q4 2019. For claims-based measures, the quarters used in this scenario are Q1 2018 through Q4 2019.

(2) *COVID–19 Affected Reporting (CAR) Scenario:* We calculated IRF QRP measures using 3 quarters (Q2 2019 through Q4 2019) of IRF QRP data for assessment-based measures, and 6 quarters (Q1 2018 through Q4 2018 and Q3 2019 through Q4 2019) for claims-based measures. The CAR scenario uses the most recently available data to simulate the public health emergency reality where quarters 1 and 2 of a calendar year must be excluded from calculation. Quarterly trends in IRF–PAI assessment-based and IRF claims-based measures indicate that these measures do not exhibit substantial seasonal variation.

To assess performance in these scenarios, we calculated the reportability as the percent of IRFs meeting the case minimum for public reporting (the public reporting threshold). To test the reliability of restricting the IRFs included in the SPR Base Scenario to those included in the CAR Scenario, we performed three tests on the set of IRFs included in both scenarios. First, we evaluated measure correlation using the Pearson and Spearman correlation coefficients, which assess the alignment of IRFs' provider scores. Second, for each scenario, we conducted a split-half reliability analysis and estimated intraclass correlation (ICC) scores, where higher scores imply better internal reliability. Modest differences in ICC scores between both scenarios would suggest that using fewer quarters of data does not impact the internal reliability of the results. Third, we estimated reliability scores where a higher value indicates that measure scores are relatively consistent for patients admitted to the same IRF and variation in the measure reflects true differences across providers. To calculate the reliability results, we restricted the IRFs included in the SPR scenario included in the CAR scenario.

Our testing indicated that the expected impact of using fewer quarters of data on reportability and reliability of IRF–PAI assessment-based measures and IRF claims-based measures is acceptable.

We proposed to use the CAR scenario as the approach for the following affected refreshes: For IRF–PAI assessment-based measures, the affected refresh is the December 2021 refresh; for claims-based measures, the affected refreshes occur from December 2021 through June 2023. For the earlier three affected refreshes (March, June, and September 2021), we decided to hold constant the Care Compare website with December 2020 data. We communicated this decision in a Public Reporting Tip Sheet, which is located at *https://www.cms.gov/files/document/irfqrp-covid19prtipsheet-october-2020.pdf.*

Our proposal of the CAR approach for the affected refreshes would allow us to begin displaying more recent data in December 2021, rather than continue displaying December 2020 data (Q1 2019 through Q4 2019 for assessment-based measures, Q4 2017 through Q3 2019 for claims-based measures). We believe that resuming public reporting refreshes starting in December 2021 with fewer quarters of data can assist consumers by providing more recent quality data as well as more actionable data for IRF providers. Our testing results indicate we can achieve these positive impacts with acceptable changes in reportability and reliability. Table 11 summarizes the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for assessment-based measures. Table 12 summarizes the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for claims-based measures.

We invited public comments on the proposal to use the CAR scenario to publicly report IRF measures for the December 2021–June 2023 refreshes.

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TABLE 11: Schedule for Refreshes Affected by COVID-19 PHE Exemptions for IRF-PAI Assessment--based QMs

Quarter Refresh	IRF-PAI Assessment Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
December 2020	Q1 2019 – Q4 2019 (4)
March 2021	Q1 2019 – Q4 2019 (4)
June 2021	Q1 2019 – Q4 2019 (4)
September 2021	Q1 2019 – Q4 2019 (4)
December 2021	Q3 2020 – Q1 2021 (3)
March 2022	Q3 2020 – Q2 2021 (4)* *Normal reporting resumes with 4 quarters of data.

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

TABLE 12: Schedule for Refreshes Affected by COVID-19 PHE Exemptions for IRF Claims--based QMs

Quarter Refresh	Claims-based Quarters in Schedule for Care Compare (number of quarters)
December 2020	Q4 2017 – Q3 2019 (8)
March 2021	Q4 2017 – Q3 2019 (8)
June 2021	Q4 2017 – Q3 2019 (8)
September 2021	Q4 2017 – Q3 2019 (8)
December 2021	Q4 2018 – Q4 2019, Q3 2020 (6)
March 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
June 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
September 2022	Q4 2019, Q3 2020 – Q3 2021 (6)
December 2022	Q4 2019, Q3 2020 – Q3 2021 (6)
March 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
June 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
September 2023	Q4 2020 – Q3 2022 (8)* *Normal reporting resumes with 8 quarters of data.

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

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The following is a summary of the public comments received on the proposed revisions to use the CAR scenario to publicly report IRF measures for the December 2021–June 2023 refreshes and our responses:

Comment: We received a few comments on the COVID–19 Affected Reporting (CAR) scenario methodology proposed. Two commenters stated that the CAR scenario appeared to adequately ensure data reportability and reliability and also requested that CMS continue to monitor the modified Care Compare refreshes until normal reporting resumes to ensure the CAR scenario produces valid and reliable results. One commenter recommended that CMS continue using the Standard Public Reporting (SPR) base scenario, stating that it is more consistent and logical to use a continuous time-period rather than a mixture of time periods. Three commenters who disagreed with the CAR methodology did not provide specific alternative methods. However, they encouraged CMS to engage with stakeholders to determine alternative methods for updating Care Compare.

Response: We thank the commenters for their support. Regarding the use of the SPR scenario, the use of *only* continuous time periods would have the effect of excluding one or more quarters of data (beyond the already excluded Q1 and Q2 2020 quarters) from measure calculations, resulting in a longer freeze of the measures on Care Compare. Thus, we believe the CAR scenario to be a more appropriate choice moving forward. We agree that it will be critical to monitor measures to identify any concerning trends, and we will continue to do so as part of its routine monitoring activities to regularly assess measure performance, reliability, and reportability for all data submitted for the IRF QRP.

Comment: Most commenters expressed their appreciation for the flexibility that CMS offered to IRFs during the early months of the COVID–19 PHE in granting an exception to the IRF QRP reporting requirements from

Q1 2020 (January 1, 2020 through March 31, 2020) and Q2 2020 (April 1, 2020 through June 30, 2020). However, a number of commenters raised concerns with CMS' proposal to utilize fewer than the standard number of quarters for public reporting of quality measures on Care Compare, since it will still include Q3 2020 (July 1, 2020 through September 30, 2020) and Q4 2020 (October 1, 2020 through December 31, 2020). Several commenters are concerned that the proposed public reporting schedule would utilize data submitted while the country was still under a PHE, particularly during the proposed Q3 2020 and Q4 2020 timeframes. A few commenters pointed out that the pandemic community infection rate surged repeatedly across different regions of the country. One commenter noted in some parts of the country the highest infection rates occurred after IRFs resumed collecting QRP data in Q3 2020. Another commenter raised concern that with fewer quarters being reported, more weight would be assigned to data reported for Q3 and Q4 2020. Several commenters urged CMS to exclude the entire calendar year 2020 data.

Response: While we understand that there are concerns related to the use of Q3 and Q4 2020 data, we do not believe that further exempting providers from QRP reporting requirements, nor the continued suspension of public reporting, are actionable solutions. We granted a 6-month exception to IRF QRP reporting requirements related to the PHE for COVID–19 under 42 CFR 412.634(c)(4)(i) of our regulations, a sufficient timeframe for IRFs to adjust to the change in care patterns associated with the PHE for COVID–19. We further believe that the public display of quality data is extremely important, and the continued need for access to IRF quality data on Care Compare by CMS beneficiaries outweighs any potential provider impacts.

We conducted testing to inform our decisions about publicly reporting data for refreshes using Q3 and Q4 2020 As discussed in section VII.H.3.c of the FY 2021 IRF PPS proposed rule (86 FR 19114 through 19115), the testing helped us develop a plan that we believe meets acceptable standards for public reporting. IRFs that believe they were disproportionately affected by the PHE may apply for an individual exception or extension to the IRF QRP reporting requirement for Q3 and/or Q4 2020. We direct readers to our regulations at 42 CFR 412.634(c). Instructions for requesting an extraordinary circumstances exemption (ECE) may be found on the IRF QRP Reconsideration and Exception and Extension web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Reconsideration-and-Exception-and-Extension.*

Comment: One commenter stated that public reporting should be frozen until the first quarter after the end of the PHE.

Response: We disagree with the commenter about freezing the data until after the first quarter of the end of the PHE. Care Compare provides a single user-friendly interface that patients and caregivers can use to make informed decisions about healthcare based on cost, quality of care, volume of services, and other data. COVID–19 has caused CMS to take a number of actions to further protect IRF patients. Resuming public reporting will inform patients and families of more recent information on quality of care provided in IRFs. As we progress, CMS will analyze the quality measures for any significant changes, and take any actions needed to continue the improvement and protection of patient health and safety.

Comment: One commenter requested that CMS include a notation on Care Compare to explain the temporary adjustments made for the PHE. Another commenter expressed concern that the public would not have the necessary context required to interpret the data that were collected during the pandemic.

Response: We will notify consumers of the use of fewer quarters of data reported on Care Compare when the website is refreshed. However, we do not believe that posting additional explanation on how IRF measure scores may or may not be affected by the ongoing PHE would be helpful. Such messages would give the impression the data posted on Care Compare are inaccurate or cannot be used when making informed healthcare decisions, which is not the case given the extensive testing CMS conducts.

Comment: One commenter suggested that CMS conduct a complete review and update the entire Care Compare platform and its reporting metrics while the website is in a data freeze, including removing measures that are outdated.

Response: On September 3, 2020, we announced the launch of Care Compare, a streamlined redesign of eight legacy CMS healthcare compare tools that were available on Medicare.gov, including Inpatient Rehabilitation Facility Compare. We will continue to enhance the information available to patients, families, and consumers, so they can more easily learn about the quality of care nursing homes provide.

After careful consideration of the public comments, we are finalizing our proposal to use the CAR scenario to publicly report IRF measures for the December 2021–June 2023 refreshes as proposed without modification.

d. Update on Data Freeze and December 2021 Public Reporting Methodology for NHSN-Based Measures

CDC recommends using the four most recent non-contiguous non-exempted quarters of data for NHSN reporting in the IRF QRP. This non-contiguous compilation of quarterly reporting would continue until the time when four contiguous quarters of reporting resumes (based on CDC's review, this would occur in July 2022). Tables 13 and 14 display the original schedules for public reporting of IRF CDI NHSN and CAUTI NHSN measures and the HCP Influenza NHSN measure, respectively. Tables 15 and 16 summarize the revised schedule and the proposed schedules for IRF CDI and CAUTI NHSN measures and the HCP Influenza measure, respectively.

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TABLE 13: IRF Quarters in Care Compare Original Schedule for Refreshes Affected by COVID-19 PHE Exemptions – CDI and CAUTI NHSN Measures

Quarter Refresh	CDI and CAUTI Quarters in Original Schedule for Care Compare (number of quarters)
Actual December 2020 (on Care Compare)	Q4 2018 – Q3 2019 (4)*
Original December 2020	Q1 2019 – Q4 2019 (4)
March 2021	Q2 2019 – Q1 2020 (4)
June 2021	Q3 2019 – Q2 2020 (4)
September 2021	Q4 2019 – Q3 2020 (4)
December 2021	Q1 2020 – Q4 2020 (4)
March 2022	Q2 2020 – Q1 2021 (4)
June 2022	Q3 2020 – Q2 2021 (4)

*The September 2020 refresh was postponed to December 2020 for technical reasons.

TABLE 14: IRF Quarters in Care Compare Original Schedule for Refreshes Affected by COVID-19 PHE Exemptions – HCP Influenza Measure

Quarter Refresh	HCP Influenza Quarters in Original Schedule for Care Compare (number of quarters)
Actual December 2020 (on Care Compare)	Q4 2017 – Q1 2018 (2)*
Original December 2020	Q4 2018 – Q1 2019 (2)
March 2021	Q4 2018 – Q1 2019 (2)
June 2021	Q4 2018 – Q1 2019 (2)
September 2021	Q4 2018 – Q1 2019 (2)
December 2021	Q4 2019 – Q1 2020 (2)
March 2022	Q4 2019 – Q1 2020 (2)
June 2022	Q4 2019 – Q1 2020 (2)
September 2022	Q4 2019 – Q1 2020 (2)
December 2022	Q4 2020 – Q1 2021 (2)

*The September 2020 refresh was postponed to December 2020 for technical reasons.

TABLE 15: Schedule for Refreshes Affected by COVID-19 PHE Exemptions for the CDI and CAUTI NHSN Measures

Quarter Refresh	CDI and CAUTI Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
December 2020	Q4 2018 – Q3 2019 (4)
March 2021	Q4 2018 – Q3 2019 (4)
June 2021	Q4 2018 – Q3 2019 (4)
September 2021	Q4 2018 – Q3 2019 (4)
December 2021	Q1 2019 – Q4 2019 (4)
March 2022	Q2 2019 – Q4 2019, Q3 2020 (4)
June 2022*	Q3 2020 – Q2 2021 * Normal reporting resumes with 4 contiguous quarters of data.

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

TABLE 16: Schedule for Refreshes Affected by COVID-19 PHE Exemptions for the HCP Influenza NHSN Measure

Quarter Refresh	HCP Influenza Quarters in Schedule for Care Compare (number of quarters)
December 2020	Q4 2017 – Q1 2018 (2)
March 2021	Q4 2017 – Q1 2018 (2)
June 2021	Q4 2017 – Q1 2018 (2)
September 2021	Q4 2017 – Q1 2018 (2)
December 2021	Q4 2018 – Q1 2019 (2)
March 2022	Q4 2018 – Q1 2019 (2)
June 2022	Q4 2018 – Q1 2019 (2)
September 2022	Q4 2018 – Q1 2019 (2)
December 2022	Q4 2020 – Q1 2021 (2)* * Normal reporting resumes.

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

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The following is a summary of the public comments received on the proposed schedules for IRF CDI and CAUTI NHSN measures and the HCP Influenza measure and our responses:

Comment: We received one comment regarding the appropriateness of reporting Q3 and Q4 2020 data, where the commenter believes that using Q3 and Q4 2020 data is problematic and an alternative methodology is required.

Response: As described above in our response to comments regarding the general use of Q3 and Q4 2020 data, we do not believe that further exempting providers from QRP reporting requirements, nor the continued suspension of public reporting, are actionable solutions. We further believe that the public display of quality data is extremely important, and the continued need for access to provider quality data on Care Compare by CMS beneficiaries outweighs any potential provider impacts.

After careful consideration of the public comment received, we are finalizing our proposal to publicly report the IRF CDI and CAUTI NHSN measures and the HCP Influenza measure using the four most recent non-contiguous non-exempted quarters of data until the time when four contiguous quarters of reporting resumes.

IX. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues

A. Fee Schedule Adjustments for Accessories (Including Seating Systems) and Seat and Back Cushions Furnished in Connection With Group 3 or Higher Complex Rehabilitative Power Wheelchairs and Complex Rehabilitative Manual Wheelchairs

1. Background

For additional details on Medicare fee schedule payments for DMEPOS and specifically for wheelchairs and wheelchair accessories, see the interim final rule with comment period entitled ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas'' (83 FR 21912 through 21925).

a. Medicare Coding and Payment for Wheelchairs

In 1989, Medicare began making payment for durable medical equipment (DME) using fee schedule amounts calculated from supplier charges for furnishing the equipment during the 1980s, increased by annual update factors specified under the statute. In 1994, CMS in collaboration with the wheelchair manufacturing industry and national associations representing wheelchair suppliers and manufacturers replaced all Healthcare Common Procedure Coding System (HCPCS) codes and statutorily-mandated fee schedule amounts for wheelchairs with new codes and fee schedule amounts for wheelchair ''bases'' and separate codes for ''options'' or accessories furnished in connection with the various wheelchair bases. For example, a separate HCPCS code K0040 and payment was created for an adjustable angle footplate used on the various wheelchair bases. The fee schedule amounts for the separately paid and covered wheelchair options/accessories did not vary based on the type of wheelchair base furnished with the option/accessory.

Complex rehabilitative wheelchairs are generally used by patients with severe impairments. Such wheelchairs may have features such as specialty seating systems that can tilt the patient into various positions and special controls such as sip and puff versus a standard joystick. In general, the first codes for complex rehabilitative manual wheelchairs, which include adult and pediatric size wheelchairs with special seating systems, were added to the HCPCS in January 2003, although code K0005 for ultralight-weight manual wheelchairs was added to the HCPCS in 1994 and was later classified as a complex rehabilitative wheelchair in 2012. The first codes for complex rehabilitative power wheelchairs were added to the HCPCS in November 2006. These wheelchairs are further separated into ''Group 2'' and ''Group 3'' wheelchair bases based on performance capabilities such as speed, distance, and obstacle clearance. The fee schedule amounts initially established for the separately coded features such as power seating systems and sip and puff controls did not vary depending on whether they were furnished in connection with a Group 2 complex rehabilitative power wheelchair or a Group 3 complex rehabilitative power wheelchair.

b. DMEPOS Competitive Bidding Program (CBP)

Section 1847(a) of the Act mandates the implementation of the Medicare DMEPOS CBP in competitive bidding areas (CBAs) throughout the United States for contract award purposes for the furnishing of competitively priced items and services falling under three main categories specified in paragraph (2) of such section of the Act:

- Off-the-shelf (OTS) orthotics, for which payment would otherwise be made under section 1834(h) of the Act;
- Enteral nutrients, equipment, and supplies described in section 1842(s)(2)(D) of the Act; and
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

Certain DME items are excluded from the DMEPOS CBP in section 1847(a)(2)(A), including certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs). More recently, section 106(a) of the FCAA excluded complex rehabilitative manual wheelchairs (as determined by the Secretary), and certain manual wheelchairs (identified, as of October 1, 2018, by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor to such codes) and related accessories when furnished in connection with such wheelchairs from the DMEPOS CBP.

Wheelchair accessories frequently furnished in connection with manual wheelchairs include adjustable armrests, headrests, anti-tipping devices, safety belts and harnesses, adjustable angle footplates, and seat and back cushions. These accessories were included under the CBP when furnished in connection with standard manual wheelchairs from July 2013 through December 2018. Wheelchair accessories frequently furnished in connection with power wheelchairs include batteries, adjustable armrests, headrests, elevating leg rests, safety belts and harnesses, and seat and back cushions. These accessories were included under the CBP when furnished in connection with standard power wheelchairs from January 2011 through December 2018 and when furnished in connection with Group 2 complex rehabilitative power wheelchairs from January 2011 through December 2013. Wheelchair accessories frequently furnished uniquely in connection with complex rehabilitative power wheelchairs include power seating systems, special interface controls (for example, sip and puff versus joystick), and expandable controllers and other special electronics. These accessories were included under the CBP when furnished in connection with Group 2 complex rehabilitative power wheelchairs from January 2011 through December 2013. Complex rehabilitative manual wheelchairs have never been included in the CBP.

c. Group 3 or Higher Complex Rehabilitative Power Wheelchairs and Related Accessories Excluded From the CBP

Complex rehabilitative power wheelchairs classified as groups 2 and 3 were included in Round 1 of the DMEPOS CBP. Section 154(a)(1)(A) of Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (Pub. L. 110–275) amended section 1847(a)(1) of the Act to add paragraph (D) which terminated Round 1 of the DMEPOS CBP and required rebidding Round 1 for the same items and services and the same areas with some changes. Section 154(a)(1)(B) of MIPPA amended section 1847(a)(2)(A) of the Act to exclude group 3 or higher complex rehabilitative power wheelchairs and related accessories when furnished in connection with such wheelchairs from the DMEPOS CBP. Since we included group 2 complex rehabilitative power wheelchairs and related accessories (including seating systems) and seat and back cushions in Round 1 of the DMEPOS CBP, we were required to include those wheelchairs and accessories in the Round 1 Rebid of the DMEPOS CBP. The accessories (including seating systems) and seat and back cushions furnished in connection with group 2 complex rehabilitative power wheelchairs (HCPCS codes K0835 through K0843) are the same items furnished in connection with group 3 complex rehabilitative power wheelchairs (HCPCS codes K0848 through K0864). Standard power wheelchairs and related accessories were also included in the Round 1 Rebid and included accessories such as batteries that are used in both complex rehabilitative and standard power wheelchairs but did not include accessories that are only used with complex rehabilitative power wheelchairs such as power seating systems and specialty interface controls (for example, sip and puff).

The contract performance period and single payment amounts under the Round 1 Rebid of the DMEPOS CBP became effective on January 1, 2011, in the nine Round 1 Rebid areas. Therefore, contract suppliers received the single payment amounts established under the CBP for furnishing group 1 and 2 standard power wheelchair bases, group 2 complex rehabilitative power wheelchair bases, and the interchangeable accessories used with the different bases (for example, batteries used with all power wheelchairs and power seating systems used with both group 2 and 3 complex rehabilitative power wheelchairs) in the Round 1 Rebid areas. As noted above, we did not competitively bid group 3 complex rehabilitative power wheelchairs or accessories used with a group 3 complex rehabilitative power wheelchair in the Round 1 Rebid of the DMEPOS CBP, as such items were excluded from the CBP under section 1847(a)(2)(A) of the Act. Although group 2 complex rehabilitative power wheelchair bases and accessories furnished in connection with these wheelchairs were included in the Round 1 Rebid of the DMEPOS CBP, these items were not included in subsequent rounds of the DMEPOS CBP due to the low number of claims and expenditures associated with these items and our determination that including these items under the DMEPOS CBP would not result in significant savings. However, these items could be included in future rounds of the DMEPOS CBP if the number of claims and expenditures associated with these items increases.

d. Fee Schedule Adjustments

Section 1834(a)(1)(F)(ii) of the Act mandates that in the case of ''covered items'' furnished on or after January 1, 2016, information on the payment determined under the CBP shall be used to adjust the fee schedule amounts for an area that is not a competitive bidding area. Section 1834(a)(13) of the Act defines covered items as durable medical equipment and medical supplies. The ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' final rule establishing the methodology for using CBP payments to adjust fee schedule amounts was issued on November 6, 2014 (79 FR 66120). We issued a specific rule under § 414.210(g)(5) for accessories used with different types of wheelchair base equipment, such as batteries furnished in connection with standard power wheelchairs, as well as Group 2 complex rehabilitative power wheelchairs (79 FR 66223 through 66233). Our intent was that this standard fee schedule adjustment methodology would apply to both

wheelchair accessories furnished in connection with wheelchairs that were not included under the CBP, such as batteries or power seating systems furnished in connection with Group 3 complex rehabilitative power wheelchairs, as well as wheelchair accessories furnished in connection with wheelchairs that were included in the CBP. In that rulemaking, we stated the Agency's belief that it would be unnecessarily burdensome to have different fee schedule amounts for the same item (HCPCS code) when it is used with similar, but different types of base equipment, and that the costs of furnishing the accessory should not vary significantly based on the type of base equipment it is used with (79 FR 66230). We began adjusting the fee schedule amounts for these common wheelchair accessories based on the rules in 42 CFR 414.210(g) effective on January 1, 2016.

Section 2 of the Patient Access and Medicare Protection Act of 2015 (Pub. L. 114–115) delayed the fee schedule adjustments for accessories (including seating systems) and seat and back cushions when furnished in connection with group 3 complex rehabilitative power wheelchairs until January 1, 2017. Subsequently, section 16005 of the Cures Act extended this delay in the fee schedule adjustments based on competitive bidding information from January 1, 2017 until July 1, 2017. Since Congress has acted twice to address the issue, we stated in the ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas'' interim final rule with comment period (83 FR 21912 through 21925) (hereinafter referred to as the ''May 2018 IFC'') that these legislative actions highlighted a general concern regarding access to this specialized equipment by the vulnerable patient population that depends on this equipment and technology (83 FR 21919).

We discussed in the May 2018 IFC that complex rehabilitative power wheelchairs are used by patients needing functionality, such as head or sip and puff controls, power tilt or recline seating, or ventilators mounted to the wheelchair, which are not available on standard power wheelchairs. The ability and performance of the wheelchair in meeting the patients' specialized needs is critical, and most patients use wheelchair bases with group 3 level performance to meet these needs. Far fewer use group 2 wheelchair bases, which are the bases that the accessories were included with under Round 1 of the DMEPOS CBP.

Section 1847(a)(2)(A) of the Act provides the categories of items that are subject to the CBP and excludes certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs). We stated in the May 2018 IFC that this statutory exclusion should inform our implementation of section 1834(a)(1)(F) of the Act such that the fee schedule amounts for wheelchair accessories and back and seat cushions used in conjunction with group 3 complex rehabilitative power wheelchairs should not be adjusted based on the methodologies set forth in § 414.210(g)(5). Therefore, as we announced in guidance available on the CMS website in June 2017 (located at *https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.html*), we stated in the May 2018 IFC that the fee schedule amounts for wheelchair accessories and back and seat cushions used in conjunction with group 3 power wheelchairs would continue to be based on the unadjusted fee schedule amounts updated by the covered item update specified in section 1834(a)(14) of the Act. In the May 2018 IFC (83 FR 21919) and continuation notice in 2021 (86 FR 21949), we stated that the fee schedule amounts for all other accessories and cushions used with other wheelchairs would continue to be adjusted based on information from the CBP. We are changing our position in this final rule; this payment policy for wheelchair accessories and back and seat cushion used in conjunction with group 3 power wheelchairs would also apply for accessories used in conjunction with complex rehabilitative manual wheelchairs for the reasons articulated below.

We note that recently section 106(a) of the FCAA excluded complex rehabilitative manual wheelchairs and (as determined by the Secretary), and certain manual wheelchairs (identified, as of October 1, 2018, by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor to such codes) and related accessories from the DMEPOS CBP. In addition, section 106(b) of this Act excluded accessories (including seating systems) and seat and back cushions when furnished in connection with these manual wheelchairs from fee schedule adjustments based on information from the DMEPOS CBP from January 1, 2020, through June 30, 2021. On June 23, 2021, we announced in guidance that we would continue the unadjusted fee schedule rates for these manual wheelchair accessories through the quarter beginning July 1, 2021. We stated in the guidance that we would continue these payment rates based on several factors. Beneficiaries with disabilities such as amyotrophic lateral sclerosis, cerebral palsy, multiple sclerosis, muscular dystrophy, spinal cord injury, and traumatic brain injury often rely on complex rehabilitative wheelchairs and accessories to maximize their function and independence. It is important to avoid any potential operational difficulties for suppliers, our partners in the Medicaid program, or private payers that have elected to rely on the DMEPOS fee schedule that could result from frequent updates to the Medicare fee schedules. Finally, this action is consistent with prior Medicare program policy actions related to similar accessories for complex power rehabilitative wheelchairs as described in section 2 of the Patient Access and Medicare Protection Act of 2015.

We received 5 timely pieces of correspondence containing comments on the May 2018 IFC regarding fee schedule adjustments for accessories (including seating systems) and seat and back cushions for Group 3 or higher complex rehabilitative power wheelchairs. The comments were from wheelchair suppliers and manufacturers as well as a patient advocacy organization.

The following is a summary of the public comments received on the Fee Schedule Amounts for Accessories Used with Group 3 Complex Rehabilitative Power Wheelchairs policy included in the May 2018 IFC and our responses:

Comment: All of the commenters supported the policy to continue paying unadjusted fee schedule amounts for accessories (including seating systems) and seat and back cushions furnished in connection with group 3 or higher complex rehabilitative power wheelchairs and recommended that the same policy be applied to wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with complex rehabilitative manual wheelchairs. Commenters stated that this would ensure access to complex rehabilitative wheelchair technology Medicare beneficiaries with significant disabilities depend on for functionality and that these needs are just as important for manual wheelchair users as they are for power wheelchair users. One commenter stated that the functionality that complex rehabilitative technology provides enhances lives and prevents painful, costly and wholly preventable hospital visits and is as

needed by a person using a manual wheelchair as it is by a person using a power wheelchair. One commenter noted that Congress has acted several times to protect complex rehabilitative wheelchair technology from payment reductions and that CMS should use its authority to do the same. One commenter stated that applying competitive bidding pricing to accessories used in connection with complex rehabilitative manual wheelchairs and not to accessories used in connection with complex rehabilitative power wheelchairs creates a disparity in that people with disabilities who use complex rehabilitative manual wheelchairs have less access to needed accessories than those using complex rehabilitative power wheelchairs and that there should be equal access for all beneficiaries who use complex rehabilitative wheelchairs.

One commenter indicated that complex rehabilitative wheelchair accessories are designed to meet a unique clinical need and are costlier to provide than standard wheelchair accessories. They also indicated that since these special accessories are not used on standard wheelchair bases, they are not items that have been included in the CBP because only standard wheelchair bases and related accessories have been included in the CBP. They stated that CMS is using information obtained through the competitive bidding of accessories used on standard wheelchairs and inappropriately applying that pricing to complex rehabilitative accessories that were not part of the CBP. This commenter indicated that the June 2017 policy clarification posted on the CMS website regarding application of competitive bidding pricing on accessories for complex rehabilitative power wheelchairs should have also applied to accessories for complex rehabilitative manual wheelchairs as well.

Response: We agree with the commenters that the issues faced by wheelchair users with significant disabilities who depend on complex rehabilitative wheelchair technology for functionality and to avoid adverse health outcomes is vitally important for this special population of wheelchair users and that this issue is no different for users of complex rehabilitative manual wheelchairs than it is for users of complex rehabilitative power wheelchairs. As noted above by a commenter, Congress has acted several times with regards to both manual and power complex rehabilitative wheelchair technology to exempt such technology from pricing reductions stemming from the CBP, specifically fee schedule adjustments based on competitive bidding pricing for accessories (including seating systems) and seat and back cushions when furnished with either Group 3 or higher complex rehabilitative power wheelchairs or complex rehabilitative manual wheelchairs. We believe that we should be consistent in applying our policies regarding pricing of accessories (including seating systems) and seat and back cushions when furnished with either Group 3 or higher complex rehabilitative power wheelchairs and complex rehabilitative manual wheelchairs to safeguard beneficiaries with significant disabilities who rely on this technology to function independently on a daily basis.

After consideration of the public comments received, we are finalizing our policy to exempt accessories (including seating systems) and seat and back cushions furnished in connection with Group 3 or higher complex rehabilitative power wheelchairs from the fee schedule adjustments using prices for these items when furnished with standard power wheelchairs or Group 2 complex rehabilitative power wheelchairs under the CBP.

Further, in light of the comments that we believe correctly point out that this issue is the same for complex rehabilitative manual wheelchairs as it is for Group 3 or higher complex rehabilitative power wheelchairs, we are extending this policy to also exempt accessories (including seating systems) and seat and back cushions furnished in connection with complex rehabilitative manual wheelchairs and other complex manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008 from the fee schedule adjustments based on information from the CBP. We agree with commenters that these accessories (including seating systems) and seat and back cushions are different items when furnished in connection with Group 3 or higher complex rehabilitative power wheelchairs or complex rehabilitative manual wheelchair bases, and that if these wheelchairs are excluded from the CBP by statute, then the wheelchairs and related accessories should also be excluded from the fee schedule adjustments. We believe that the combination of the more complex wheelchair bases and accessories and seat and back cushions furnished with those bases make up a completely different covered DME item than the combination of the less complex wheelchair bases and accessories and seat and back cushions. In addition, the statute excludes both related accessories furnished in connection with Group 3 or higher complex rehabilitative power wheelchair bases and more recently complex rehabilitative manual wheelchair bases from the CBP. Complex rehabilitative manual wheelchairs and manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008 and related accessories were not included in previous rounds of the DMEPOS CBP, and therefore, single payment amounts from the DMEPOS CBP are not available for these items. In light of comments received on this general issue, we now believe it would not be accurate or appropriate to rely on single payment amounts established under the DMEPOS CBP based on bids submitted by suppliers who are not required to use assistive technology providers to adjust the fee schedule amounts for more complex wheelchairs for patients with significant disabilities who depend on these important items to function every hour of the day.

Therefore, we are finalizing an exemption for accessories (including seating systems) and seat and back cushions furnished in connection with Group 3 or higher complex rehabilitative power wheelchairs from the fee schedule adjustments under section 1834(a)(1)(F) of the Act. In light of comments received in response to the May 2018 IFC, and out of an abundance of caution, we are also extending this exemption to accessories (including seating systems) and seat and back cushions furnished in connection with complex rehabilitative manual wheelchairs. We agree with commenters that we should treat these accessories (including seating systems) and seat and back cushions the same whether they are furnished in connection with Group 3 or higher complex rehabilitative power wheelchair or complex rehabilitative manual wheelchair bases. We note that these items are excluded from the CBP and therefore the fee schedule amounts should not be adjusted based on information from the CBP. We also note again that Congress has acted several times to delay or prohibit fee schedule adjustments for these items, and this final rule will continue to protect these items from fee schedule adjustments based on information from the DMEPOS CBP. Notably, such information from the CBP (single payment amounts) was calculated based on bids from suppliers who furnished these cushions and accessories in connection with different wheelchair bases, so we now believe this information is inapplicable in the context of payment for complex

rehabilitative manual wheelchairs and their cushions and accessories.

B. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs From the DMEPOS Competitive Bidding Program (CBP)

Section 106(a) of the FCAA amended section 1847(a)(2)(A) of the Act to exclude complex rehabilitative manual wheelchairs, (as determined by the Secretary), certain manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor codes, and related accessories from the DMEPOS CBP. Therefore, as part of the ''Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)'' proposed rule (85 FR 70358 through 70414) (hereinafter referred to as the ''November 2020 proposed rule''), we proposed to make conforming changes to the definition of ''item'' under § 414.402 to reflect that these wheelchairs and related accessories are excluded from the DMEPOS CBP. We proposed to edit the definition of item in § 414.402 to exclude ''power wheelchairs, complex rehabilitative manual wheelchairs, manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, and related accessories when furnished in connection with such wheelchairs.''

In addition, section 106(b) of the FCAA mandated that, during the period beginning on January 1, 2020 and ending June 30, 2021, CMS not adjust the Medicare fee schedule amounts for wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with complex rehabilitative manual wheelchairs (determined by the Secretary as HCPCS codes E1161, E1231, E1232, E1233, E1234 and K0005) and certain manual wheelchairs currently described by HCPCS codes E1235, E1236, E1237, E1238, and K0008 based on information from the CBP. We implemented the changes to the fee schedule amounts for these items through program instructions based on the discretion provided by the FCAA.

We received 11 timely comments on the November 2020 proposed rule regarding excluding complex rehabilitative manual wheelchairs, certain other manual wheelchairs, and related accessories furnished in connection with these wheelchairs from the CBP. The comments were from wheelchair suppliers and manufacturers, as well as a national coalition of consumers and clinicians advocating for access to and coverage of assistive devices and technologies for persons with injuries, illnesses, disabilities, and chronic conditions of all ages.

The following is a summary of the public comments received on our proposal to revise the definition of ''item'' under § 414.402 to reflect that complex rehabilitative manual wheelchairs and related accessories are excluded from the DMEPOS CBP and our responses:

Comment: All commenters supported the exclusion of the complex rehabilitative manual wheelchairs, other manual wheelchairs and related accessories furnished in connection with these wheelchairs from the DMEPOS CBP.

Response: We thank the commenters for supporting the provisions of the proposed rule.

Comment: Several commenters stated that the accessories for these wheelchairs should also be permanently excluded from fee schedule adjustments based on pricing for the accessories when furnished in connection with other wheelchairs included under the CBP. Commenters stated that section 1834(a)(1)(F) of the Act requires CMS to adjust the fee schedule rates for ''covered items,'' defined as DMEPOS included in the CBP, when the same items are furnished outside of CBAs. The commenters noted that Congress excluded complex rehabilitative manual wheelchairs and related accessories from the CBP, and therefore, they cannot be ''covered items'' as defined by section 1834(a)(1)(F) of the Act that can be subject to CBP-based adjustments. They stated that complex rehabilitative manual wheelchairs and related accessories are not CBP items, and therefore, CMS has no data from the CBP for these covered items that they can use to adjust the fee schedule amounts for such items when furnished outside of competitive bidding areas. Commenters also stated that in 2017, CMS recognized the same implication in the context of complex rehabilitative power wheelchairs and related accessories, which Congress excluded from the CBP and, by extension, prohibited any CBP-based adjustments to their fee schedule amounts. Commenters noted that CMS, via subregulatory guidance posted on its website, stated that the statutory exclusion of complex rehabilitative power wheelchairs and related accessories under section 1847(a)(2)(A) of the Act should ''inform [the agency's] implementation of section 1834(a)(1)(F) . . . such that fee schedule amounts for wheelchair *accessories and seat cushions* used in conjunction with group 3 complex rehabilitative power wheelchairs would not be adjusted based on the methodologies in § 414.210(g)(5).'' The commenters noted that this same rationale supports a permanent exemption for complex rehabilitative manual wheelchairs and related accessories because of the enactment of section 106(a) of the FCAA and the corresponding exclusion of complex rehabilitative manual wheelchairs and related accessories from the CBP.

Response: We agree with the commenters that complex rehabilitative manual wheelchairs and certain other complex manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008 and related accessories should be exempt from the fee schedule adjustments under section 1834(a)(1)(F) of the Act and address this issue in detail under section III of this final rule.

After consideration of the public comments we received, we are finalizing the proposal to revise the definition of ''item'' under § 414.402 to conform with section 106(a) of the FCAA. The new definition of item appears in the regulation text of this final rule. In addition, as discussed in section III. of this final rule, based on public comments we received in response to the May 2018 IFC, we are finalizing a fee schedule adjustment exemption for accessories (including seating systems) and cushions used with complex manual wheelchairs and other complex manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008. We agree with commenters that we should treat these accessories (including seating systems) and seat and back cushions the same whether they are furnished in connection with a Group 3 or higher complex rehabilitative power wheelchair or complex rehabilitative manual wheelchair bases. We note that these items are excluded from the CBP and therefore the fee schedule amounts should not be adjusted based on information from the CBP.

X. Miscellaneous Comments

Comment: We received several additional comments that were outside the scope of the FY 2022 IRF PPS proposed rule. Specifically, we received comments regarding the facility-level adjustment factors, the inclusion of recreational therapy, and rehabilitation physician training and experience.

Response: We thank the commenters for bringing these issues to our attention, and will take these comments

into consideration for potential policy refinements.

Comment: We received a comment in response to the proposed adoption of the COVID–19 Vaccination Coverage among HCP measure for the IRF QRP recommending CMS assess Immunization Information Systems (IIS).

Response: This comment falls outside the scope of the FY 2022 IRF PPS proposed rule.

Comment: One commenter provided a document that included a series of proposed Care Compare reforms. Another commenter provided comments relative to documentation requirements, therapy requirements, prior authorization of managed care organizations, burden in the appeals process, regulatory flexibility for participation in alternative payment models, improving PAC navigability, and changes for specialty hospitals.

Response: We thank the commenter for these suggestions, and will take these comments into consideration for potential Care Compare refinements.

XI. Provisions of the Final Regulations

In this final rule, we are adopting the provisions set forth in the FY 2022 IRF PPS proposed rule (86 FR 19086), specifically:

- We will update the CMG relative weights and average length of stay values for FY 2022, in a budget neutral manner, as discussed in section V. of this final rule.
- We will update the IRF PPS payment rates for FY 2022 by the market basket increase factor, based upon the most current data available, with a productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section VI. of this final rule.
- We will update the FY 2022 IRF PPS payment rates by the FY 2022 wage index and the labor-related share in a budget-neutral manner, as discussed in section VI. of this final rule.
- We will calculate the final IRF standard payment conversion factor for FY 2022, as discussed in section VI. of this final rule.
- We will update the outlier threshold amount for FY 2022, as discussed in section VII. of this final rule.
- We will update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2022, as discussed in section VII. of this final rule.

The policy changes and updates to the IRF QRP for FYs 2022 and 2023 are as follows:

- Updates to quality measures and reporting requirements under the IRF QRP.

In this final rule, we are also adopting certain policy changes and provisions set forth in the interim final rule with comment period entitled ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas'' (83 FR 21912 through 21925) and the proposed rule entitled ''Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)'' (85 FR 70358 through 70414) as follows:

- Changes to exclude complex rehabilitative manual wheelchairs, certain other manual wheelchairs, and accessories furnished in connection with these wheelchairs from the DMEPOS CBP.
- Changes to exclude Group 3 or higher CRT power wheelchairs and accessories furnished in connection with these wheelchairs from the fee schedule adjustments under section 1834(a)(1)(F) of the Act.

In this final rule, we are also extending the fee schedule adjustment exclusion for Group 3 or higher CRT power wheelchairs and accessories furnished in connection with these wheelchairs to complex rehabilitative manual wheelchairs, certain other manual wheelchairs, and accessories furnished in connection with these wheelchairs as well.

XII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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 OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA 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; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This final rule does not impose any new information collection requirements as outlined in the regulation. However, this final rule does make reference to an associated information collection that is not discussed in the regulation text contained in this document. The following is a discussion of this information collection, which has already received OMB approval.

As stated in section VII.C. of the FY 2022 IRF PPS proposed rule, for purposes of calculating the IRF Annual Increase Factor (AIF), we proposed that IRFs submit data on one new quality measure: COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) beginning with the FY 2023 IRF QRP. The aforementioned measure will be collected via the following means.

A. COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure

IRFs will submit data for this quality measure using the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN). Data submission by the NHSN occurs via a web-based tool hosted by the CDC. This reporting service is provided free of charge to healthcare facilities, including IRFs. IRFs currently utilize the NHSN for purposes of meeting other IRF QRP requirements.

We note that the CDC would account for the burden associated with the COVID–19 Vaccination Coverage among HCP measure collection under OMB control number 0920–1317 (expiration 1/31/2024). Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660, enacted on November 14, 1986 (NCVIA)).[91] However, we refer readers to section X.C.7. of the FY 2022 IRF PPS proposed rule, where we provided an estimate of the burden and cost to IRFs, and the CDC will include it in a revised information collection request for 0920–1317.

In section VII.C.2. of the proposed rule, we proposed to update the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure to exclude residents discharged

[91] Section 321 of the NCVIA provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

home under the care of an organized home health service or hospice. This measure was adopted in the FY 2020 IRF PPS final rule (84 FR 39099 through 39107) and burden accounted for in OMB control number 0938–0842 (expiration December 31, 2022). The finalized update to the measure's denominator does not affect the information collection burden already established.

XIII. Regulatory Impact Analysis

A. Statement of Need

This final rule updates the IRF prospective payment rates for FY 2022 as required under section 1886(j)(3)(C) of the Act and in accordance with section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before August 1 before each FY, the classification and weighting factors for CMGs used under the IRF PPS for such FY and a description of the methodology and data used in computing the prospective payment rates under the IRF PPS for that FY. This final rule also implements section 1886(j)(3)(C) of the Act, which requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2012 and subsequent years.

Furthermore, this final rule adopts policy changes under the statutory discretion afforded to the Secretary under section 1886(j) of the Act. We are also finalizing updates to quality measures and reporting requirements under the IRF QRP. In addition, this final rule finalizes a Medicare provision adopted in an interim final rule with comment period (IFC) issued on May 11, 2018 related to fee schedule adjustments for wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with group 3 or higher complex rehabilitative power wheelchairs as well as changes to the regulations related to implementation of section 106(a) of the FCAA.

B. Overall Impact

We have examined the impacts of this rule 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 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Section (6)(a) of Executive Order 12866 provides that a regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate the total impact of the policy updates described in this final rule by comparing the estimated payments in FY 2022 with those in FY 2021. This analysis results in an estimated $130 million increase for FY 2022 IRF PPS payments. Additionally, we estimate that costs associated with the proposal to update the reporting requirements under the IRF QRP result in an estimated $489,536.16 addition to costs in FY 2022 for IRFs. We also estimate a $170 million dollar increase in Medicare payments for the provisions related to paying higher rates for wheelchair accessories used with complex power and manual wheelchairs for the period from FY 2022 to FY 2026. Based on our estimates OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act).

Note that the Medicare DMEPOS provisions related to wheelchair accessories are assumed to add a total of $170 million dollars in increased Medicare payments to the overall impact of the rule from FY 2022 to FY 2026.

Also, the rule has been reviewed by OMB. Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

C. Anticipated Effects

1. Effects on IRFs and DME Suppliers

a. Effects on IRFs

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, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IRFs and most other providers and suppliers are small entities, either by having revenues of $8.0 million to $41.5 million or less in any 1 year depending on industry classification, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432 at *https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf,* effective January 1, 2017 and updated on August 19, 2019.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs or the proportion of IRFs' revenue that is derived from Medicare payments. Therefore, we assume that all IRFs (an approximate total of 1,114 IRFs, of which approximately 54 percent are nonprofit facilities) are considered small entities and that Medicare payment constitutes the majority of their revenues. HHS generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 17, we estimate that the net revenue impact of this final rule on all IRFs is to increase estimated payments by approximately 1.5 percent. The rates and policies set forth in this final rule will not have a significant impact (not greater than 3 percent) on a substantial number of small entities. The estimated impact on small entities is shown in Table 17. MACs are not considered to be small entities. Individuals and states are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 604 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 fewer than 100 beds. As shown in Table 17, we estimate that the net revenue impact of this final rule on rural IRFs is to increase estimated payments by approximately 1.6 percent based on the data of the 133 rural units and 12 rural hospitals in our database of 1,114 IRFs for which data were available. We estimate an overall impact for rural IRFs in all areas between –0.1 percent and 3.0 percent. The Secretary hereby certifies that this final rule will not have a significant impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–04, enacted on March 22, 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. In 2021, that threshold is approximately $158 million. This final rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. As stated, this final rule will not have a substantial effect on state and local governments, preempt state law, or otherwise have a federalism implication.

b. Effects on DME Suppliers

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. The DMEPOS provisions of this rule are not considered to have a significant impact on a substantial number of small entities as payments continue at their current levels.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. The DMEPOS provisions of this rule are not considered to have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the 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. In 2021, that threshold is approximately $158 million. The DMEPOS provisions of this rule do not mandate any requirements for State, local, or tribal governments, or for the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. As stated, the DMEPOS provisions of this final rule will not have a substantial effect on state and local governments, preempt state law, or otherwise have a federalism implication.

2. Detailed Economic Analysis

This final rule will update the IRF PPS rates contained in the FY 2021 IRF PPS final rule (85 FR 48424). Specifically, this final rule will update the CMG relative weights and ALOS values, the wage index, and the outlier threshold for high-cost cases. This final rule will apply a productivity adjustment to the FY 2022 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act.

We estimate that the impact of the changes and updates described in this final rule would be a net estimated increase of $130 million in payments to IRF providers. The impact analysis in Table 17 of this final rule represents the projected effects of the updates to IRF PPS payments for FY 2022 compared with the estimated IRF PPS payments in FY 2021. We determine the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. Although some of these changes may not necessarily be specific to the IRF PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon IRFs.

In updating the rates for FY 2022, we are implementing the standard annual revisions described in this final rule (for example, the update to the wage index and market basket increase factor used to adjust the Federal rates). We are also reducing the FY 2022 IRF market basket increase factor by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. We estimate the total increase in payments to IRFs in FY 2022, relative to FY 2021, would be approximately $130 million.

This estimate is derived from the application of the FY 2022 IRF market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, which yields an estimated increase in aggregate payments to IRFs of $160 million. However, there is an estimated $30 million decrease in aggregate payments to IRFs due to the update to the outlier threshold amount. Therefore, we estimate that these updates would result in a net increase in estimated payments of $130 million from FY 2021 to FY 2022.

The effects of the updates that impact IRF PPS payment rates are shown in Table 17. The following updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the update to the outlier threshold amount, from approximately 3.4 percent to 3.0 percent of total estimated payments for FY 2022, consistent with section 1886(j)(4) of the Act.
- The effects of the annual market basket update (using the IRF market basket) to IRF PPS payment rates, as required by sections 1886(j)(3)(A)(i) and (j)(3)(C) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act.
- The effects of applying the budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.
- The effects of the budget-neutral changes to the CMG relative weights and ALOS values under the authority of section 1886(j)(2)(C)(i) of the Act.
- The total change in estimated payments based on the FY 2022 payment changes relative to the estimated FY 2021 payments.

3. Description of Table 17

Table 17 shows the overall impact on the 1,114 IRFs included in the analysis.

The next 12 rows of Table 17 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership; all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and all rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 969 IRFs located in urban areas included in our analysis. Among these, there are 665 IRF units of hospitals located in urban areas and 304 freestanding IRF hospitals located in urban areas. There are 145 IRFs located in rural areas included in our analysis. Among these, there are 133 IRF units of hospitals located in rural areas and 12 freestanding IRF hospitals located in rural areas. There are 407 for-profit IRFs. Among these, there are 373 IRFs in urban areas and 34 IRFs in rural areas. There are 599 non-profit IRFs. Among these, there are 509 urban IRFs and 90 rural IRFs. There are 108 government-owned IRFs. Among these, there are 87 urban IRFs and 21 rural IRFs.

The remaining four parts of Table 17 show IRFs grouped by their geographic location within a region, by teaching status, and by DSH patient percentage (PP). First, IRFs located in urban areas are categorized for their location within a particular one of the nine Census geographic regions. Second, IRFs located in rural areas are categorized for their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each policy described in this rule to the facility categories listed are shown in the columns of Table 17. The description of each column is as follows:

- Column (1) shows the facility classification categories.
- Column (2) shows the number of IRFs in each category in our FY 2022 analysis file.
- Column (3) shows the number of cases in each category in our FY 2022 analysis file.
- Column (4) shows the estimated effect of the adjustment to the outlier threshold amount.
- Column (5) shows the estimated effect of the update to the IRF labor-related share and wage index, in a budget-neutral manner.
- Column (6) shows the estimated effect of the update to the CMG relative weights and ALOS values, in a budget-neutral manner.
- Column (7) compares our estimates of the payments per discharge, incorporating all of the policies reflected in this final rule for FY 2022 to our estimates of payments per discharge in FY 2021.

The average estimated increase for all IRFs is approximately 1.5 percent. This estimated net increase includes the effects of the IRF market basket increase factor for FY 2022 of 1.9 percent update based on an IRF market basket update of 2.6 percent, less a 0.7 percentage point productivity adjustment, as required by section 1886(j)(3)(C)(ii)(I) of the Act. It also includes the approximate 0.4 percent overall decrease in estimated IRF outlier payments from the update to the outlier threshold amount. Since we are making the updates to the IRF wage index, labor-related share and the CMG relative weights in a budget-neutral manner, they will not be expected to affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will be expected to affect the estimated distribution of payments among providers.

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TABLE 17: IRF Impact Table for FY 2022 (Columns 4 through 7 in percentage)

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 22 Wage Index and Labor Share	CMG Weights	Total Percent Change [1]
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Total	1,114	381,770	-0.4	0.0	0.0	1.5
Urban unit	665	150,120	-0.6	0.1	-0.2	1.2
Rural unit	133	19,484	-0.6	0.4	-0.3	1.4
Urban hospital	304	207,312	-0.2	-0.1	0.2	1.8
Rural hospital	12	4,854	-0.1	0.4	0.1	2.3
Urban For-Profit	373	200,172	-0.2	0.0	0.2	1.9
Rural For-Profit	34	7,988	-0.2	0.3	0.0	2.0
Urban Non-Profit	509	137,347	-0.6	-0.1	-0.2	1.0
Rural Non-Profit	90	13,571	-0.7	0.5	-0.3	1.4
Urban Government	87	19,913	-0.6	0.5	-0.3	1.5
Rural Government	21	2,779	-0.4	0.3	-0.3	1.5
Urban	969	357,432	-0.4	0.0	0.0	1.5
Rural	145	24,338	-0.5	0.4	-0.2	1.6
Urban by region						
Urban New England	31	14,531	-0.3	-0.6	-0.2	0.8
Urban Middle Atlantic	125	43,217	-0.4	-1.0	0.0	0.5
Urban South Atlantic	154	74,192	-0.3	0.5	0.0	2.2
Urban East North Central	157	45,939	-0.4	0.0	-0.1	1.4
Urban East South Central	55	25,615	-0.2	0.0	0.1	1.8
Urban West North Central	75	20,395	-0.4	0.7	-0.2	2.0
Urban West South Central	191	80,374	-0.3	-0.3	0.2	1.5
Urban Mountain	82	28,228	-0.2	0.1	0.0	1.7
Urban Pacific	99	24,941	-0.7	0.5	-0.2	1.5
Rural by region						
Rural New England	5	1,264	-0.5	-0.2	-0.4	0.7
Rural Middle Atlantic	10	989	-1.0	1.0	-0.4	1.6
Rural South Atlantic	16	3,976	-0.2	1.1	0.2	3.0
Rural East North Central	23	3,931	-0.5	0.6	-0.2	1.8
Rural East South Central	21	3,702	-0.3	0.1	-0.3	1.4
Rural West North Central	20	2,872	-0.7	0.0	-0.4	0.8
Rural West South Central	42	6,760	-0.5	0.3	-0.2	1.5
Rural Mountain	5	486	-0.9	0.7	-0.5	1.2
Rural Pacific	3	358	-1.4	0.1	-0.7	-0.1
Teaching status						
Non-teaching	1,008	337,505	-0.3	0.0	0.0	1.6
Resident to ADC less than 10%	59	29,605	-0.4	0.1	0.0	1.6
Resident to ADC 10%-19%	36	13,318	-0.7	-0.4	-0.2	0.5
Resident to ADC greater than 19%	11	1,342	-0.4	0.0	-0.4	1.1
Disproportionate share patient percentage (DSH PP)						

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 22 Wage Index and Labor Share	CMG Weights	Total Percent Change [1]
DSH PP = 0%	49	8,050	-0.6	-0.9	0.1	0.5
DSH PP <5%	143	52,695	-0.3	-0.2	0.1	1.5
DSH PP 5%-10%	280	116,312	-0.3	0.1	0.1	1.8
DSH PP 10%-20%	387	139,160	-0.4	-0.1	0.0	1.4
DSH PP greater than 20%	255	65,553	-0.5	0.2	-0.1	1.5

[1]This column includes the impact of the updates in columns (4), (5), and (6) above, and of the IRF market basket update for FY 2022 (2.6 percent), reduced by 0.7 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

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4. Impact of the Update to the Outlier Threshold Amount

The estimated effects of the update to the outlier threshold adjustment are presented in column 4 of Table 17.

For the FY 2022 proposed rule, we used preliminary FY 2020 IRF claims data, and, based on that preliminary analysis, we estimated that IRF outlier payments as a percentage of total estimated IRF payments would be 3.3 percent in FY 2022. As we typically do between the proposed and final rules each year, we updated our FY 2020 IRF claims data to ensure that we are using the most recent available data in setting IRF payments. Therefore, based on updated analysis of the most recent IRF claims data for this final rule, we estimate that IRF outlier payments as a percentage of total estimated IRF payments are 3.4 percent in FY 2022. Thus, we are adjusting the outlier threshold amount in this final rule to maintain total estimated outlier payments equal to 3 percent of total estimated payments in FY 2022. The estimated change in total IRF payments for FY 2022, therefore, includes an approximate 0.4 percentage point decrease in payments because the estimated outlier portion of total payments is estimated to decrease from approximately 3.4 percent to 3 percent.

The impact of this outlier adjustment update (as shown in column 4 of Table 17) is to decrease estimated overall payments to IRFs by 0.4 percentage point.

5. Impact of the Wage Index and Labor-Related Share

In column 5 of Table 17, we present the effects of the budget-neutral update of the wage index and labor-related share. The changes to the wage index and the labor-related share are discussed together because the wage index is applied to the labor-related share portion of payments, so the changes in the two have a combined effect on payments to providers. As discussed in section VI.C. of this final rule, we are updating the labor-related share from 73.0 percent in FY 2021 to 72.9 percent in FY 2022.

6. Impact of the Update to the CMG Relative Weights and ALOS Values.

In column 7 of Table 17, we present the effects of the budget-neutral update of the CMG relative weights and ALOS values. In the aggregate, we do not estimate that these updates will affect overall estimated payments of IRFs. However, we do expect these updates to have small distributional effects.

7. Effects of Requirements for the IRF QRP for FY 2022

In accordance with section 1886(j)(7)(A) of the Act, the Secretary must reduce by 2 percentage points the annual market basket increase factor otherwise applicable to an IRF for a fiscal year if the IRF does not comply with the requirements of the IRF QRP for that fiscal year. In section VII.A of this final rule, we discussed the method for applying the 2 percentage point reduction to IRFs that fail to meet the IRF QRP requirements. As discussed in section VIII C. of this final rule, we are finalizing the adoption of one measure to the IRF QRP beginning with the FY 2023 IRF QRP, the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure, and finalizing our proposal to update the denominator of the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure beginning with the FY 2023 IRF QRP. As discussed in section VIII.G. of this final rule, we are finalizing the CDC/NHSN web-based surveillance system for data submission for the COVID–19 Vaccination Coverage among HCP measure. As discussed in section VIII.H., we are finalizing two public reporting policies. The first is to publicly report the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the September 2022 Care Compare refresh or as soon as technically feasible based on data collected for Q4 2021 (October 1, 2021 through December 31, 2021) using the most recent quarter of data. Second, we are finalizing use of the CAR scenario to publicly report IRF QRP measures for the December 2021–June 2023 refreshes and to publicly report the NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717), the NHSN Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138), and the NHSN Influenza Vaccination among HCP (NQF #0431) measure using the four most recent non-contiguous non-exempted quarters of data until the time when four contiguous quarters of reporting resumes.

We believe that the burden associated with the IRF QRP is the time and effort associated with complying with the requirements of the IRF QRP. The finalized IRF QRP requirements add no additional burden to the active collection under OMB control number 0938–0842 (expiration 12/31/2022). Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the NCVIA. However, CMS has provided an estimate of burden and cost for IRFs here, and the CDC will include it in a revised information collection request for 0920–1317. Consistent with the CDC's experience of collecting data

using the NHSN, we estimate that it would take each IRF an average of 1 hour per month to collect data for the COVID–19 Vaccination Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. We believe it would take an administrative assistant from 45 minutes up to 1 hour and 15 minutes to enter this data into NHSN. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages from the U.S. Bureau of Labor Statistics' (BLS) May 2019 National Occupational Employment and Wage Estimates.[92] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 18.

TABLE 18: U.S. Bureau of Labor and Statistics' May 2019 National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean Hourly Wage ($/hr)	Overhead and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Administrative Assistant	43-6013	$18.31	$18.31	$36.62

Based on the time range, it would cost each IRF between $27.47 and $45.78 each month or an average cost of $36.62 each month, and between $329.64 and $549.36 each year. We believe the data submission for the COVID–19 Vaccination Coverage among HCP measure would cause IRFs to incur additional average burden of 12 hours per year for each IRF and a total annual burden of 13,368 hours across all IRFs. The estimated annual cost across all 1,114 IRFs in the U.S. for the submission of the COVID–19 Vaccination Coverage among HCP measure would range from $367,218.96 and $611,987.04 with an average of $489,536.16.

We recognize that many IRFs may also be reporting other COVID–19 data to HHS. However, we believe the benefits of reporting data on the COVID–19 Vaccination Coverage among HCP measure to assess whether the potential spread of COVID–19 among their HCP, and the risk of transmission of COVID–19 within IRFs, and to help sustain the ability of IRFs to continue serving their communities throughout the PHE and beyond outweigh the costs of reporting. We received no comments on the estimated time to collect data and enter it into NHSN.

8. Effects of Requirements for the DMEPOS Provisions

a. Fee Schedule Adjustments for Accessories (Including Seating Systems) and Seat and Back Cushions Furnished in Connection With Group 3 or Higher Complex Rehabilitative Power Wheelchairs and Complex Rehabilitative Manual Wheelchairs

In this final rule, we are finalizing a policy exempting wheelchair accessories furnished in connection with Group 3 complex rehabilitative power wheelchairs from fee schedule adjustments based on information from the DMEPOS CBP. The cost of this provision is estimated to be $130 million dollars in increased Medicare payments with $30 million dollars in increased beneficiary copayments from FY 2022 to FY 2026. This cost can be considered in the FY 2022 President's budget baseline. We are also finalizing a policy exempting wheelchair accessories furnished in connection with complex rehabilitative manual wheelchairs from fee schedule adjustments based on information from the DMEPOS CBP. This policy was not reflected in the FY 2022 President's budget baseline and has an estimated cost of $40 million dollars in increased Medicare payments with $10 million dollars in increased beneficiary copayments from FY 2022 to FY 2026.

b. Exclusion of Complex Rehabilitative Manual Wheelchairs and Certain Other Manual Wheelchairs From the DMEPOS CBP

This rule finalizes conforming changes to the regulations at 42 CFR 414.402 to revise the definition of ''item'' at 42 CFR 414.402 under the CBP to exclude complex rehabilitative manual wheelchairs and certain other wheelchairs from the CBP and is estimated to have no fiscal impact and is considered in the baseline of the FY 2022 President's Budget.

D. Alternatives Considered

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this final rule.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services.

As noted previously in this final rule, section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2022. Thus, in accordance with section 1886(j)(3)(C) of the Act, we update the IRF prospective payments in this final rule by 1.9 percent (which equals the 2.6 percent estimated IRF market basket increase factor for FY 2022 reduced by a 0.7 percentage point productivity adjustment as determined under section 1886(b)(3)(B)(xi)(II) of the Act (as required by section 1886(j)(3)(C)(ii)(I) of the Act)).

We considered utilizing FY 2019 claims data to update the prospective payment rates for FY 2022 due to the potential effects of the PHE on the FY 2020 IRF claims data. However, it has been our long-standing practice to utilize the most recent full fiscal year of data to update the prospective payment rates, as this data is generally considered to be the best overall predictor of experience in the upcoming fiscal year. Additionally, the FY 2019 data does not reflect any of the changes to the CMG definitions or the data used to classify IRF patients into CMGs that became effective in FY 2020 and will continue to be used in FY 2022. As such, we believe it would be appropriate to utilize FY 2020 data to update the prospective payment rates for FY 2022 at this time. While we believe maintaining our existing methodology of utilizing the most recent available IRF data to update the prospective payment rates for FY 2022 is appropriate, we solicited comment in the FY 2020 proposed rule on the use of FY 2019 data to update the prospective payment rates for FY 2022.

[92] *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed on March 30, 2021.

For more information on the proposed FY 2022 estimated impacts utilizing FY 2019 claims data, we refer readers to the FY 2022 IRF PPS proposed rule (86 FR 19086). As the comments received in response to this solicitation are pertinent to the updates in this final rule, we are providing a summary of the feedback we received from stakeholders regarding this solicitation in this final rule.

The following is a summary of the comments received on the use of FY 2019 data to update the prospective rates for FY 2022 and our responses:

Comment: In general, the majority of commenters supported the use of FY 2020 data to update the prospective payment rates for FY 2022. Several commenters suggested that FY 2020 data should be used to update the payment rates for FY 2022 as these data reflect changes in IRF care related to the pandemic and will therefore be more likely to reflect IRF utilization in FY 2022, as COVID–19 will continue to impact IRFs in the future. Additionally, these commenters supported the use of FY 2020 data noting that it reflects changes to the CMG definitions that were implemented in FY 2020 and that will continue to be used in FY 2022. In contrast, a few commenters expressed concern with the proposed use of FY 2020 data to update the prospective payment rates for FY 2020 and recommended that CMS use FY 2019 data for this purpose. These commenters stated that they believe the FY 2020 data was heavily impacted by the pandemic and would result in skewed relative weights and an inflated outlier threshold and suggested that FY 2019 data would be more likely to reflect IRF utilization in FY 2022 as the pandemic continues to subside. A few of these commenters requested that CMS use FY 2019 claims data to update the relative weights and the outlier threshold while other commenters requested that CMS maintain the relative weights and outlier threshold at the current FY 2021 levels for FY 2022.

Response: We appreciate the commenters' support of using FY 2020 data to update the prospective payment rates for FY 2022. It has been our longstanding practice to use the most recent full fiscal year of claims data available to update the prospective payment rates as we believe this data is reflective of the current Medicare IRF population and is generally the best overall predictor of experience in the upcoming fiscal year. We also agree with the commenters' recommendation to use FY 2020 data for rate setting purposes as this data reflects the changes to the CMG definitions that were implemented in FY 2020 and that will continue to be used in FY 2022.

We appreciate the commenters' feedback regarding how the PHE has impacted individual facilities and acknowledge that the PHE impacted many aspects of IRF operations. However, we disagree with the commenters' assertions that the FY 2020 claims data were impacted by the PHE to the extent that they would be unsuitable to use for payment updates under the IRF PPS. An analysis of FY 2020 IRF claims data indicates that admissions under the IRF PPS dropped by approximately 7 percent overall compared to FY 2019. Decreased admissions were observed across almost all conditions in the IRF setting, with the largest declines occurring among patients treated for lower-extremity joint replacements and pain syndrome. However, there were only slight changes observed in the share of IRF admissions across all RICs in FY 2020 compared to FY 2019. For example, the share of IRF admissions for lower-extremity joint replacements dropped from 3.7 percent in FY 2019 to 3.0 percent in FY 2020, while the share of IRF admissions for pain syndrome dropped from 0.3 percent in FY 2019 to 0.2 percent in FY 2020.

Additionally, we attempted to approximate changes in IRF utilization in the FY 2020 IRF claims data that could be attributable to the PHE. When the PHE for COVID–19 was declared, we announced a number of waivers to provide regulatory flexibilities to IRF providers. When submitting claims under these waivers, IRFs billed Medicare using a ''DR'' condition code on the claim. To approximate the number of IRF stays for admissions that would not have been expected in the absence of the PHE, we identified claims that included a COVID–19 ICD–10 diagnosis code and claims that could be considered waiver admissions, as identified by the presence of a ''DR'' condition code on the claim. While we are not able to definitively identify claims that are solely attributable to the PHE based on the presence of a COVID–19 diagnosis code or waiver code on the claim, this methodology allows us to understand the overall utilization of the waivers and the overall frequency of COVID–19 diagnoses among the IRF population. This analysis indicated that approximately 1.0 percent of IRF stays included a COVID–19 ICD–10 diagnosis code, while 4.2 percent of IRF stays could be considered waiver admissions. This would suggest that the FY 2020 IRF claims data were not disproportionally impacted by the PHE, as the overwhelming majority of IRF beneficiaries entered into IRF stays in FY 2020 as they would have in any other year. Therefore, we believe this data is representative of typical IRF utilization of the current Medicare population and would therefore be appropriate to use when updating the prospective payment rates for FY 2022, as well as updates to the outlier threshold and the relative weights.

We do not believe it would be appropriate to freeze the outlier threshold and the relative weights at their current FY 2021 levels for FY 2022. The annual updates to the outlier threshold and the relative weights are intended to better align IRF payments with the costs of caring for IRF patients and to ensure that IRFs will be appropriately compensated for treating unusually high-cost patients while taking into account changes in IRF utilization as well as changes in estimated costs and payments from year to year. Therefore, we believe it is appropriate to update these values for FY 2022 using FY 2020 claims data, as proposed in the FY 2022 proposed rule.

Comment: One commenter suggested that CMS try to isolate the effects of the PHE in the IRF setting and recommended that CMS exclude claims with a COVID–19 diagnosis and claims considered to be wavier admissions from the 2020 data when setting the outlier threshold as these claims may be atypical.

Response: As discussed above, we are not able to definitively identify claims that are directly attributable to the PHE, such as IRF stays that would not qualify for IRF level services in the absence of the PHE, solely based on the presence of a COVID–19 diagnosis code or waiver code on the claim. Additional information beyond the presence of these codes would be necessary to determine if the stay would qualify for IRF level services through review of IRF medical records. However, given the significant amount of resources that would be required to complete a comprehensive review of the medical records for these cases by both IRFs and CMS contractors we do not believe this undertaking is feasible at this time. As such, we do not believe it would be appropriate to exclude claims from, or otherwise apply adjustments to, the underlying pool of claims data that is used to determine adjustments to the IRF prospective payment rates. We also agree with the commenters' assertion that IRFs will continue to be impacted by the PHE in the near future and therefore it would be appropriate to maintain claims with a COVID–19 ICD–10 diagnosis code in the methodology used to determine adjustments under

the IRF PPS as IRFs will continue to treat patients with a COVID–19 diagnosis in the near future.

Comment: A few commenters noted analysis presented in other proposed payment rules related to other Medicare settings and indicated that the proposal to use FY 2020 data to update the IRF prospective payment rates for FY 2022 was inconsistent with CMS' proposed policies in other Medicare settings. Some commenters requested that additional data and analysis be shared with stakeholders to allow them to more fully assess the effects of the pandemic in the IRF setting and encouraged us to continue evaluating the effects of the PHE and to provide additional analysis in future years.

Response: The proposed use of FY 2020 claims data to update the prospective payment rates for FY 2022 was based on analysis of both FY 2019 and FY 2020 IRF claims data. As discussed above, we did not observe increases and decreases in IRF utilization in the FY 2020 claims data of the same magnitude observed in other Medicare settings and described in other Medicare proposed rules. As such, we believe it would be appropriate to use the FY 2020 IRF claims data to update the prospective payment rates for FY 2022. We appreciate the commenters' feedback regarding the types of information that would be most useful to them in assessing the effects of the PHE in the IRF setting. We also appreciate the commenters' concerns regarding the impacts of the PHE in the IRF setting and will continue to monitor the IRF data to ensure that IRF payments are appropriately aligned with costs of care.

After careful consideration of the comments we received in response to this solicitation, we are finalizing the use of FY 2020 claims data, as described in the FY 2022 proposed rule, to update the prospective rates for FY 2022.

We considered maintaining the existing CMG relative weights and ALOS values for FY 2022. However, in light of recently available data and our desire to ensure that the CMG relative weights and ALOS values are as reflective as possible of recent changes in IRF utilization and case mix, at this time we believe that it is appropriate to update the CMG relative weights and ALOS values using FY 2020 claims data to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We also considered maintaining the existing outlier threshold amount for FY 2022. As outlier payments are a redistribution of payment, it is important to adjust the outlier threshold amount to maintain the targeted 3 percent outlier pool as closely as possible. Maintaining an outlier threshold that would yield estimated outlier payments greater than 3 percent would leave less payment available to cover the costs of non-outlier cases. Therefore, analysis of updated FY 2020 data indicates that estimated outlier payments would be greater than 3 percent of total estimated payments for FY 2022, by approximately 0.4 percent. Consequently, we are adjusting the outlier threshold amount in this final rule to reflect a 0.4 percentage point decrease thereby setting the total outlier payments equal to 3 percent, instead of 3.4 percent, of aggregate estimated payments in FY 2022.

E. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final 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 the rule, we assume that the total number of unique commenters on the FY 2022 IRF PPS proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the FY 2022 IRF PPS proposed rule in detail, and it is also possible that some reviewers chose not to comment on the FY 2022 proposed rule. For these reasons, we thought that the number of commenters would be a fair estimate of the number of reviewers of this final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the national mean hourly wage data from the May 2020 BLS for Occupational Employment Statistics (OES) for medical and health service managers (SOC 11–9111), we estimate that the cost of reviewing this rule is $114.24 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 would take approximately 3 hours for the staff to review half of this final rule. For each reviewer of the rule, the estimated cost is $342.72 (3 hours × $114.24). Therefore, we estimate that the total cost of reviewing this regulation is $1,137,144.96 ($342.72 × (2,668 IRF reviewers and 650 DME reviewers).

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Tables 19, 20, and 21, we have prepared accounting statements showing the classification of the expenditures associated with the provisions of this final rule. Table 19 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the updates presented in this final rule based on the data for 1,114 IRFs in our database. Tables 20 and 21 provides our best estimate of the impacts associated with the DME provisions in this final rule.

TABLE 19: Accounting Statement: Classification of Estimated Expenditure

	Category	Transfers
Change in Estimated Transfers from FY 2021 IRF PPS to FY 2022 IRF PPS	Annualized Monetized Transfers	$130 million
	From Whom to Whom?	Federal Government to IRF Medicare Providers
Change in Estimated Costs from FY2021 IRF QRP to FY 2022 IRF QRP	Annualized monetized cost in FY 2022 for IRFs due to new quality reporting program requirements	$489,536.16
Estimated Costs Associated with Review Cost for FY 2022 IRF PPS	Cost associated with regulatory review cost	$1,137,144.96

TABLE 20: DME Provision: Complex Power Wheelchair Accessories Annualization Period 2022 to 2026

Category	Transfer		
Annualized Monetized Transfer on Program Cost Sharing (in $Millions)	**Estimate**	**Year Dollar**	**Discount Rate**
	$20	2022	7%
	$20	2022	3%
From Whom to Whom?	Federal Government to Medicare suppliers		
Annualized Monetized Transfer on Beneficiary Cost Sharing (in $millions)	**Estimate**	**Year Dollar**	**Discount Rate**
	$6	2022	7%
	$6	2022	3%
From Whom to Whom?	Beneficiaries to Medicare suppliers		

TABLE 21: Complex Manual Wheelchair Accessories Annualization Period 2022 to 2026

Category	Transfer		
Annualized Monetized Transfer on Program Cost Sharing (in $Millions)	**Estimate**	**Year Dollar**	**Discount Rate**
	$8	2022	7%
	$8	2022	3%
From Whom to Whom?	Federal Government to Medicare suppliers		
Annualized Monetized Transfer on Beneficiary Cost Sharing (in $millions)	**Estimate**	**Year Dollar**	**Discount Rate**
	$0	2022	7%
	$0	2022	3%
From Whom to Whom?	Beneficiaries to Medicare suppliers		

G. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2022 are projected to increase by 1.5 percent, compared with the estimated payments in FY 2021, as reflected in column 7 of Table 17.

IRF payments per discharge are estimated to increase by 1.5 percent in urban areas and 1.6 percent in rural areas, compared with estimated FY 2021 payments. Payments per discharge to rehabilitation units are estimated to increase 1.2 percent in urban areas and 1.4 percent in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 1.8 percent in urban areas and increase 2.3 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the policies in this final rule. The largest payment increase is estimated to be a 3.0 percent increase for rural IRFs located in the rural South Atlantic region. The analysis above, together with the remainder of this preamble, provides an RIA.

The Medicare DMEPOS provisions will continue payments for affected items at the current levels.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

Chiquita Brooks-LaSure,

Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 21, 2021.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 2. In § 414.402 amend the definition of ''Item'' by revising paragraph (1) introductory text to read as follows:

§ 414.402 Definitions.

* * * * *

Item * * *

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in § 414.202, group 3 complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, manual wheelchairs described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, and related accessories when furnished in connection with such wheelchairs, and further classified into the following categories:

* * * * *

Dated: July 27, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–16310 Filed 7–29–21; 4:15 pm]

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 413, 483, et al.

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022; and Technical Correction to Long-Term Care Facilities Physical Environment Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 413, 483 and 489

[CMS–1746–F]

RIN 0938–AU36

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022; and Technical Correction to Long-Term Care Facilities Physical Environment Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2022. In addition, the final rule includes a forecast error adjustment for FY 2022, updates the diagnosis code mappings used under the Patient Driven Payment Model (PDPM), rebases and revises the SNF market basket, implements a recently-enacted SNF consolidated billing exclusion along with the required proportional reduction in the SNF PPS base rates, and includes a discussion of a PDPM parity adjustment. In addition, the final rule includes updates for the SNF Quality Reporting Program (QRP) and the SNF Value-Based Purchasing (VBP) Program, including a policy to suppress the use of the SNF readmission measure for scoring and payment adjustment purposes in the FY 2022 SNF VBP Program because we have determined that circumstances caused by the public health emergency for COVID–19 have significantly affected the validity and reliability of the measure and resulting performance scores. We are also finalizing a technical correction to the physical environment requirements that Long-Term Care facilities must meet in order to participate in the Medicare and Medicaid programs.

DATES: These regulations are effective on October 1, 2021.

FOR FURTHER INFORMATION CONTACT:

Penny Gershman, (410) 786–6643, for information related to SNF PPS clinical issues.

Anthony Hodge, (410) 786–6645, for information related to consolidated billing, and payment for SNF-level swing-bed services.

John Kane, (410) 786–0557, for information related to the development of the payment rates and case-mix indexes, and general information.

Kia Burwell, (410) 786–7816, for information related to the wage index.

Heidi Magladry, (410) 786–6034, for information related to the skilled nursing facility quality reporting program.

Lang Le, (410) 786–5693, for information related to the skilled nursing facility value-based purchasing program.

Kristin Shifflett, (410) 786–4133, for information related to the long-term care conditions of participation.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

As discussed in the FY 2014 SNF PPS final rule (78 FR 47936), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **FEDERAL REGISTER**. Instead, these tables are available exclusively through the internet on the CMS website. The wage index tables for this final rule can be accessed on the SNF PPS Wage Index home page, at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Burwell at (410) 786–7816.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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I. Executive Summary

A. Purpose

This final rule updates the SNF prospective payment rates for fiscal year (FY) 2022 as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication of certain specified information relating to the payment update (see section II.C. of this final rule) in the **Federal Register**, before the August 1 that precedes the start of each FY. As discussed in section VI.A. of this final rule, it will also rebase and revise the SNF market basket index, including updating the base year from 2014 to 2018. As discussed in section V.D. of this final rule, it also makes revisions in the regulation text to exclude from SNF consolidated billing certain blood clotting factors and items and services related to the furnishing of such factors effective for items and services furnished on or after October 1, 2021, as required by the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, enacted December 27, 2020), as well as certain other conforming revisions. In addition, as required under section 1888(e)(4)(G)(iii) of the Act, as added by section 103(b) of the BBRA 1999, we provide for a proportional reduction in the Part A SNF PPS base rates to account for this exclusion, as described in section IV.B.6. of this final rule. We also make changes to the code mappings used under the SNF PPS for classifying patients into case-mix

groups. Additionally, this final rule includes a forecast error adjustment for FY 2022. This final rule also includes a discussion of a PDPM parity adjustment. Finally, this final rule also updates requirements for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) and the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP), including a policy to suppress the use of the SNF readmission measure for scoring and payment adjustment purposes in the FY 2022 SNF VBP Program because we have determined that circumstances caused by the public health emergency for COVID–19 have significantly affected the validity and reliability of the measure and resulting performance scores.

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and (e)(5) of the Act, the Federal rates in this final rule reflect an update to the rates that we published in the SNF PPS final rule for FY 2021 (85 FR 47594, August 5, 2020). We are also rebasing and revising the SNF market basket index, including updating the base year from 2014 to 2018. This final rule includes revisions to the regulation text to exclude from SNF consolidated billing certain blood clotting factors and items and services related to the furnishing of such factors effective for items and services furnished on or after October 1, 2021, as required by the Consolidated Appropriations Act, 2021, as well as certain conforming revisions. We are also making a required reduction in the SNF PPS base rates to account for this new exclusion. This final rule includes revisions to the International Classification of Diseases, Version 10 (ICD–10) code mappings used under PDPM to classify patients into case-mix groups. Additionally, this final rule includes a forecast error adjustment for FY 2022. This final rule also includes a discussion of a PDPM parity adjustment, used to implement PDPM in a budget neutral manner.

This final rule updates requirements for the SNF QRP, including the adoption of two new measures beginning with the FY 2023 SNF QRP: The SNF Healthcare Associated Infections (HAI) Requiring Hospitalization measure; and the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure. The COVID–19 Vaccination Coverage among HCP measure requires that SNFs use the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN) to submit data on the measure. We are also finalizing our proposal to modify the denominator for the Transfer of Health Information to the Patient—Post Acute Care (PAC) measure. Finally, we are finalizing our proposal to revise the number of quarters used for publicly reporting certain SNF QRP measures due to the public health emergency (PHE).

Additionally, we are finalizing several updates for the SNF VBP Program including a policy to suppress the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) for the FY 2022 SNF VBP Program Year for scoring, adjusting and codifying the policy at § 413.338(g). We are also updating the Phase One Review and Corrections policy to implement a claims ''snapshot'' policy which aligns the review and corrections policy for the SNF VBP Program with the review and corrections policy we use in other value-based purchasing programs and codifying the policy at § 413.338(e)(1) of our regulations. We are also making a technical update to the instructions for a SNF to request an extraordinary circumstances exception and codifying that update at § 413.338(d)(4)(ii) of our regulations. In addition, we are finalizing a technical correction to the physical environment requirements for LTC facilities by revising § 483.90(d)(1) and adding § 483.90(d)(3).

C. Summary of Cost and Benefits

TABLE 1: Cost and Benefits

Provision Description	Total Transfers/Costs
FY 2022 SNF PPS payment rate update.	The overall economic impact of this final rule is an estimated increase of $410 million in aggregate payments to SNFs during FY 2022.
FY 2022 SNF QRP changes.	The overall economic impact of this final rule is an estimated increase in cost to SNFs of $6.63 million.
FY 2022 SNF VBP changes.	The overall economic impact of the SNF VBP Program is an estimated reduction of $191.64 million in aggregate payments to SNFs during FY 2022.

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their health information.

To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) (*https://pacioproject.org/*) to facilitate collaboration with industry stakeholders to develop FHIR standards. These standards could support the exchange and reuse of patient assessment data derived from the minimum data set (MDS), inpatient rehabilitation facility patient assessment instrument (IRF–PAI), long term care hospital continuity assessment record and evaluation (LCDS), outcome and assessment information set (OASIS), and other sources. The PACIO Project has focused on FHIR implementation guides for functional status, cognitive status and new use cases on advance directives and speech, and language pathology. We encourage post-acute care (PAC) provider and health information technology (IT) vendor participation as these efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as the authoritative resource for PAC assessment data elements and their associated mappings to health IT standards such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED). The DEL furthers CMS' goal of data standardization and interoperability. When combined with digital information systems that capture and maintain these coded elements, their standardized clinical content can reduce

provider burden by supporting the exchange of standardized healthcare data; supporting provider exchange of electronic health information for care coordination, person-centered care; and supporting real-time, data driven, clinical decision making. Standards in the Data Element Library (*https://del.cms.gov/DELWeb/pubHome*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2021 ISA is available at *https://www.healthit.gov/isa.*

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. The Cures Act includes a trusted exchange framework and common agreement (TEFCA) provision [1] that will enable the nationwide exchange of electronic health information across health information networks and provide an important way to enable bi-directional health information exchange in the future. For more information on current developments related to TEFCA, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement* and *https://rce.sequoiaproject.org/.*

The ONC final rule entitled ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (85 FR 25642) published in the May 1, 2020, **Federal Register** (hereinafter referred to as ''ONC Cures Act Final Rule'') established policies related to information blocking as authorized under section 4004 of the 21st Century Cures Act. Information blocking is generally defined as a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the HHS Secretary as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information. The definition of information blocking includes a knowledge standard, which is different for health care providers than for health IT developers of certified health IT and health information networks or health information exchanges. A healthcare provider must know that the practice is unreasonable, as well as likely to interfere with access, exchange, or use of electronic health information. To deter information blocking, health IT developers of certified health IT, health information networks and health information exchanges whom the HHS Inspector General determines, following an investigation, have committed information blocking, are subject to civil monetary penalties of up to $1 million per violation. Appropriate disincentives for health care providers are expected to be established by the Secretary through future rulemaking. Stakeholders can learn more about information blocking at *https://www.healthit.gov/curesrule/final-rule-policy/information-blocking.* ONC has posted information resources including fact sheets (*https://www.healthit.gov/curesrule/resources/fact-sheets*), frequently asked questions (*https://www.healthit.gov/curesrule/resources/information-blocking-faqs*), and recorded webinars (*https://www.healthit.gov/curesrule/resources/webinars*).

We invite providers to learn more about these important developments and how they are likely to affect SNFs.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105–33, enacted August 5, 1997), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physicians' services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.*

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014) added section 1888(g) to the Act requiring the Secretary to specify an all-cause all-condition hospital readmission measure and an all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(c)(4) of the IMPACT Act amended section 1888(e)(6) of the Act, which requires the Secretary to implement a QRP for SNFs under which SNFs report data on measures and resident assessment data.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and (e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the Federal case-mix adjusted rate. The transition extended through the facility's first 3 cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full Federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted Federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2021 (85 FR 47594, August 5, 2020).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** the following:

- The unadjusted Federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

[1] ONC, Draft 2 Trusted Exchange Framework and Common Agreement, *https://www.healthit.gov/sites/default/files/page/2019-04/FINAL TEFCAQTF41719508version.pdf.*

Along with other revisions discussed later in this preamble, this final rule provides the required annual updates to the per diem payment rates for SNFs for FY 2022.

III. Analysis and Responses to Public Comments on the FY 2022 SNF PPS Proposed Rule

In response to the publication of the FY 2022 SNF PPS proposed rule, we received 338 public comments from individuals, providers, corporations, government agencies, private citizens, trade associations, and major organizations. The following are brief summaries of each proposed provision, a summary of the public comments that we received related to that proposal, and our responses to the comments.

A. General Comments on the FY 2022 SNF PPS Proposed Rule

In addition to the comments we received on specific proposals contained within the proposed rule (which we address later in this final rule), commenters also submitted the following, more general, observations on the SNF PPS and SNF care generally. A discussion of these comments, along with our responses, appears below.

Comment: Commenters submitted numerous comments and recommendations that are outside the scope of the proposed rule addressing a number of different policies, including the Coronavirus disease 2019 (COVID–19) pandemic. This included comments on the flexibilities provided to SNFs during the PHE, specifically through the waivers issued under sections 1135 and 1812(f) of the Act. Commenters also expressed concerns about the substantial additional costs due to the PHE that would be permanent due to changes in patient care, infection control staff and equipment, personal protective equipment (PPE), reporting requirements, increased wages, increased food prices, and other necessary costs. Some commenters who received CARES Act Provider Relief funds indicated that those funds were not enough to cover these costs. Additionally, a few commenters from rural areas stated that their facilities were heavily impacted from the additional costs, particularly the need to raise wages, and that this could affect patients' access to care.

Response: We greatly appreciate these comments and suggestions for revisions to policies under the SNF PPS. However, because these comments are outside the scope of the current rulemaking, we are not addressing them in this final rule. We may take them under consideration in future rulemaking.

IV. SNF PPS Rate Setting Methodology and FY 2022 Update

A. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem Federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the Federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the Federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would be payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for geographic variations in wages and for the costs of facility differences in case mix. In compiling the database used to compute the Federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA 1997 prescribed, we set the Federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas, and adjusted the portion of the Federal rate attributable to wage-related costs by a wage index to reflect geographic variations in wages.

B. SNF Market Basket Update

1. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we rebased and revised the market basket index, which included updating the base year from FY 2010 to 2014. In the proposed rule, we proposed to rebase and revise the market basket index and update the base year from 2014 to 2018. See section VI.A. of this final rule for more information.

The SNF market basket index is used to compute the market basket percentage change that is used to update the SNF Federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage update is adjusted by a forecast error correction, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section IV.B.2.d. of this final rule.

We proposed a FY 2022 SNF market basket percentage of 2.3 percent based on IGI's fourth quarter 2020 forecast of the proposed 2018-based SNF market basket (before application of the forecast error adjustment and productivity adjustment). We also proposed that if more recent data subsequently become available (for example, a more recent estimate of the market basket and/or the productivity adjustment), we would use such data, if appropriate, to determine the FY 2022 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, or productivity adjustment in the SNF PPS final rule.

Since the proposed rule, we have updated the FY 2022 market basket percentage increase based on IGI's second quarter 2021 forecast with historical data through the first quarter of 2021. The FY 2022 growth rate of the 2018-based SNF market basket is estimated to be 2.7 percent.

In section IV.B.2.e. of this final rule, we discuss the 2 percent reduction applied to the market basket update for those SNFs that fail to submit measures data as required by section 1888(e)(6)(A) of the Act.

2. Use of the SNF Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. For the Federal rates set forth in this final rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 2022. This factor is based on the FY 2022 percentage increase in the 2018-based SNF market basket index reflecting routine, ancillary, and capital-related expenses.

As stated previously, in the proposed rule, the SNF market basket percentage update was estimated to be 2.3 percent for FY 2022 based on IGI's fourth quarter 2020 forecast. For this final rule, based on IGI's second quarter 2021 forecast with historical data through the first quarter of 2021, the FY 2022 growth rate of the 2018-based SNF market basket is estimated to be 2.7 percent.

A discussion of the comments received on applying the FY 2022 SNF market basket percentage increase to the SNF PPS rates, along with our responses, may be found below.

Comment: Several commenters stated their support for the proposed FY 2022 payment update of 1.3 percent reflecting the proposed market basket update, the productivity adjustment, and the forecast error adjustment. A few commenters, while noting appreciation for the 1.3 percent update, also noted that it is very low in comparison to the increased costs they are facing as a result of the COVID–19 pandemic and that many facilities are already operating on thin margins.

Response: The proposed FY 2022 SNF payment update of 1.3 percent reflected the forecast available at that time of the market basket update, productivity adjustment, and forecast error. As stated in the proposed rule, we proposed to use the most recent forecast of data available to determine the final FY 2022 SNF payment update. The current estimate of final FY 2022 SNF payment update is 1.2 percent based on the IGI second quarter 2021 forecast of the 2018-based SNF market basket update (2.7 percent), reduced by the productivity adjustment (0.7 percentage point), and the application of the FY 2020 forecast error adjustment (−0.8 percentage point). For this final rule, we have incorporated the most recent historical data and forecasts provided by IHS Global Inc., including experience during the PHE, in order to capture the price and wage pressures facing SNFs in FY 2022. By incorporating the most recent estimates available of the market basket update and productivity adjustment, we believe these data reflect the best available projection of input price inflation faced by SNFs for FY 2022, adjusted for economy-wide productivity, which is required by statute.

Comment: The Medicare Payment Advisory Commission (MedPAC) commented that they recommend that the Congress eliminate the update to SNF payments for FY 2022. Moreover, MedPAC stated that the aggregate Medicare margin for freestanding SNFs in 2019 was 11.3 percent, the 20th consecutive year that this margin has exceeded 10 percent. MedPAC further stated that the projected margin for FY 2022 indicated that while payments might need to be reduced to more closely align them with the cost to treat beneficiaries, they also understand that the lasting impacts of COVID–19 on SNFs are uncertain which is why they proceeded cautiously in recommending no update rather than reductions to payments.

Response: We appreciate MedPAC's recommendation on the SNF annual update factor and the uncertainty for SNFs posed by the PHE. However, we are required to update SNF PPS payments by the market basket update, as required by section 1888(e)(4)(E)(ii)(IV) of the Act, and then further adjust the market basket update by the application of a productivity adjustment, as required by section 1888(e)(5)(B)(ii) of the Act. This productivity-adjusted market basket percentage update is further adjusted by a forecast error correction, if applicable.

After considering the comments received on the FY 2022 SNF market basket update factor, we are finalizing the update factor of 2.7 percent to the SNF PPS base rates for FY 2022 (prior to the application of the forecast error adjustment and productivity adjustment, which are discussed below).

3. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003 final rule (68 FR 46057 through 46059), § 413.337(d)(2) provides for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004, and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data, and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2020 (the most recently available FY for which there is final data), the forecasted or estimated increase in the SNF market basket index was 2.8 percent, and the actual increase for FY 2020 is 2.0 percent, resulting in the actual increase being 0.8 percentage point lower than the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index exceeds the 0.5 percentage point threshold, under the policy previously described (comparing the forecasted and actual increase in the market basket), the FY 2022 market basket percentage change of 2.7 percent, based on the IGI second quarter 2021 forecast, would be adjusted downward to account for the forecast error correction of 0.8 percentage point, resulting in a SNF market basket percentage change of 1.2 percent after reducing the market basket update by the productivity adjustment of 0.7 percentage point, discussed below.

In the FY 2022 SNF PPS proposed rule, we noted that we may consider modifying this forecast error methodology in future rulemaking. We invited comments and feedback on this issue, in particular on the possibility of, in future rulemaking, either eliminating the forecast error adjustment, or raising the threshold for the forecast error from 0.5 percent to 1.0 percent.

Table 2 shows the forecasted and actual market basket increases for FY 2020.

TABLE 2: Difference Between the Actual and Forecasted Market Basket Increases for FY 2020

Index	Forecasted FY 2020 Increase*	Actual FY 2020 Increase**	FY 2020 Difference
SNF	2.8	2.0	-0.8

*Published in **Federal Register**; based on second quarter 2019 IGI forecast (2014-based index).
**Based on the fourth quarter 2020 IGI forecast (2014-based index).

The following is a summary of the public comments received on the potential revisions to the forecast error adjustment and our responses:

Comment: Several commenters provided feedback on potentially modifying the SNF forecast error threshold in future rulemaking. Some commenters requested that the forecast error threshold remain the same at 0.5 percentage point. Other commenters requested that the forecast error threshold be increased to 1.0 percentage point in order to provide greater stability and certainty for year-to-year payments, while others requested that it be eliminated. One commenter recommended retaining the forecast error adjustment for the next three fiscal years at 0.5 percentage point and to then move to an alternative approach that would use a cumulative rolling projected forecast error calculation before triggering the forecast error threshold.

Response: We appreciate the commenters' responses and viewpoints on the forecast error threshold and will take them into consideration for future rulemaking.

Comment: Some commenters further stated that while they generally support the forecast error concept for the SNF PPS, given the scale of the COVID–19 disruption that occurred in FY 2020 and the associated atypical claims, they have concerns about the reliability and timing of the proposed 0.8 percentage point forecast error adjustment. Commenters stated that they believe CMS did not provide transparency in what is driving the variance between the estimated and actual 2020 market basket update and, therefore, they did not have an opportunity to comment on the data used to explain the variance. They stated that the industry experience in 2020 was that labor costs in particular were much higher than expected. A few commenters specifically requested that CMS eliminate the forecast error adjustment for FY 2022.

Response: The PHE presented many challenges to SNFs and as more complete data covering the full impact of the PHE become available we plan to monitor the information as it pertains to future rate updates and forecast error adjustments.

Pertaining to the forecast error, CMS publishes the forecasts of the market baskets (including SNF) on the CMS website (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketData*) on a quarterly basis. Additionally, as stated on the CMS website, providers can also email *DNHS@cms.hhs.gov* for further information on the market baskets. For the FY 2020 SNF market basket forecast error, this quarterly information was indicating that the error was likely to exceed the threshold of 0.5 percentage point. The final FY 2020 forecast error was only recently able to be computed using historical data through the third quarter of 2020, and this information was provided in the proposed rule. In response to commenters, we are providing a detailed breakdown of the contribution of the major market basket categories to the 0.8-percentage point forecast error: 0.4 percentage point is due to lower compensation price growth, 0.2 percentage point is due to lower Fuel, Oil, and Gas prices, and 0.2 percentage point is due to lower pharmaceutical prices. As stated in section VI.A. of this final rule, the SNF market basket is a Laspeyres-type price index that measures the prices associated with providing skilled nursing care services to Medicare beneficiaries. Cost growth is a function of price (such as the growth in average hourly wages) and quantity (such as increases in labor hours). Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured annually, these are reflected when the market basket is rebased (such as our proposal to rebase the SNF market basket to 2018). Commenters interested in the detailed 2014-based SNF market basket methodology and its underlying public data sources may refer to the FY 2018 SNF PPS final rule (82 FR 36548 through 36565).

After consideration of the comments discussed above, we are finalizing the application of the proposed forecast error adjustment without modification. As stated above, based on IGI's second quarter 2021 forecast with historical data through the first quarter of 2021, the updated FY 2022 growth rate of the 2018-based SNF market basket is estimated to be 2.7 percent. Applying the forecast error adjustment for FY 2022 results in an adjusted FY 2022 market basket update factor of 1.9 percent, which is then further reduced by the productivity adjustment discussed below.

4. Productivity Adjustment

Section 1888(e)(5)(B)(ii) of the Act, as added by section 3401(b) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) requires that, in FY 2012 and in subsequent FYs, the market basket percentage under the SNF payment system (as described in section 1888(e)(5)(B)(i) of the Act) is to be reduced annually 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, in turn, 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 FY, year, cost-reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

A complete description of the MFP projection methodology is available on our website at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* We note that, effective with FY 2022 and forward, we are changing the name of this adjustment to refer to it as the

''productivity adjustment,'' rather than the ''MFP adjustment.'' This change in terminology results in a title more consistent with the statutory language described in section 1886(b)(3)(B)(xi)(II) of the Act.

a. Incorporating the Productivity Adjustment Into the Market Basket Update

Per section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the productivity adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act being less than such payment rates for the preceding fiscal year. Thus, if the application of the productivity adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in a productivity-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted Federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

Based on the data available for the FY 2022 SNF PPS proposed rule, the estimated 10-year moving average of changes in MFP for the period ending September 30, 2022 was 0.2 percentage point. However, for this final rule, based on IGI's second quarter 2021 forecast, the estimated 10-year moving average of changes in MFP for the period ending September 30, 2022 is 0.7 percentage point.

Consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2), as discussed previously, the market basket percentage for FY 2022 for the SNF PPS is based on IGI's second quarter 2021 forecast of the SNF market basket percentage, which is estimated to be 2.7 percent. This market basket percentage is then lowered by 0.8 percentage point, due to application of the forecast error adjustment discussed above. Finally, as discussed above, we are applying a 0.7 percentage point productivity adjustment to the FY 2022 SNF market basket percentage. The resulting productivity-adjusted FY 2022 SNF market basket update is, therefore, equal to 1.2 percent, or 2.7 percent less 0.8 percentage point to account for forecast error and less 0.7 percentage point to account for the productivity adjustment.

5. Market Basket Update Factor for FY 2022

Sections 1888(e)(4)(E)(ii)(IV) and (e)(5)(i) of the Act require that the update factor used to establish the FY 2022 unadjusted Federal rates be at a level equal to the market basket index percentage change. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2020 through September 30, 2021 to the average market basket level for the period of October 1, 2021 through September 30, 2022. This process yields a percentage change in the 2018-based SNF market basket of 2.7 percent.

As further explained in section IV.B.2.c. of this final rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold in absolute terms. Since the forecasted FY 2020 SNF market basket percentage change exceeded the actual FY 2020 SNF market basket percentage change (FY 2020 is the most recently available FY for which there is historical data) by more than the 0.5 percentage point threshold, we proposed to adjust the FY 2022 market basket percentage change downward by the forecast error correction. Applying the −0.8 percentage point forecast error correction results in an adjusted FY 2022 SNF market basket percentage change of 1.9 percent (2.7 percent market basket update less 0.8 percentage point forecast error adjustment).

Section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage change by the productivity adjustment (10-year moving average of changes in MFP for the period ending September 30, 2022) which is estimated to be 0.7 percentage point, as described in section IV.B.2.d. of this final rule. Thus, we apply a net SNF market basket update factor of 1.2 percent in our determination of the FY 2022 SNF PPS unadjusted Federal per diem rates, which reflects a market basket increase factor of 2.7 percent, less the 0.8 percent forecast error correction and less the 0.7 percentage point productivity adjustment.

In the proposed rule, we noted that if more recent data become available (for example, a more recent estimate of the SNF market basket and/or MFP), we would use such data, if appropriate, to determine the FY 2022 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, or productivity adjustment in the FY 2022 SNF PPS final rule. Since more recent data did become available since the proposed rule, as outlined above, we have updated the various adjustment factors described through this section accordingly.

We also noted that section 1888(e)(6)(A)(i) of the Act provides that, beginning with FY 2018, SNFs that fail to submit data, as applicable, in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year will receive a 2.0 percentage point reduction to their market basket update for the fiscal year involved, after application of section 1888(e)(5)(B)(ii) of the Act (the productivity adjustment) and section 1888(e)(5)(B)(iii) of the Act (the 1 percent market basket increase for FY 2018). In addition, section 1888(e)(6)(A)(ii) of the Act states that application of the 2.0 percentage point reduction (after application of section 1888(e)(5)(B)(ii) and (iii) of the Act) may result in the market basket index percentage change being less than zero for a fiscal year, and may result in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 1888(e)(6)(A)(iii) of the Act further specifies that the 2.0 percentage point reduction is applied in a noncumulative manner, so that any reduction made under section 1888(e)(6)(A)(i) of the Act applies only to the fiscal year involved, and that the reduction cannot be taken into account in computing the payment amount for a subsequent fiscal year.

6. Unadjusted Federal Per Diem Rates for FY 2022

As discussed in the FY 2019 SNF PPS final rule (83 FR 39162), in FY 2020 we implemented a new case-mix classification system to classify SNF patients under the SNF PPS, the PDPM. As discussed in section V.B.1. of that final rule (83 FR 39189), under PDPM, the unadjusted Federal per diem rates are divided into six components, five of which are case-mix adjusted components (Physical Therapy (PT), Occupational Therapy (OT), Speech-Language Pathology (SLP), Nursing, and Non-Therapy Ancillaries (NTA)), and

one of which is a non-case-mix component, as existed under the previous RUG–IV model. We proposed to use the SNF market basket, adjusted as described previously, to adjust each per diem component of the Federal rates forward to reflect the change in the average prices for FY 2022 from the average prices for FY 2021. We proposed to further adjust the rates by a wage index budget neutrality factor, described later in this section. Further, in the past, we used the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. As discussed in the FY 2021 SNF PPS proposed and final rules, we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) to identify a facility's urban or rural status effective beginning with FY 2021.

For FY 2022, we note there is an additional adjustment to the unadjusted per diem base rates. Specifically, section 134 in Division CC of the Consolidated Appropriations Act, 2021 included a provision amending section 1888(e)(2)(A)(iii) of the Act so as to add ''blood clotting factors indicated for the treatment of patients with hemophilia and other bleeding disorders . . . and items and services related to the furnishing of such factors under section 1842(o)(5)(C)'' to the list of items and services excludable from the Part A SNF PPS per diem payment, effective for items and services furnished on or after October 1, 2021. We discuss this provision further in section V.B. of this final rule.

Section 1888(e)(4)(G)(iii) of the Act further requires that the Secretary ''provide for an appropriate proportional reduction in payments so that . . . the aggregate amount of such reductions is equal to the aggregate increase in payments attributable to the exclusion'' of the services from the Part A PPS per diem rates under section 1888(e)(2)(A)(iii) of the Act.

In the FY 2001 rulemaking cycle (65 FR 19202 and 46792), we established a methodology for computing such offsets in response to similar targeted consolidated billing exclusions added to section 1888(e)(2)(A)(iii) Act by section 103 of BBRA 1999. This methodology resulted in a reduction of 5 cents ($0.05) in the unadjusted urban and rural rates, using the identical data as used to establish the Part B add-on for a sample of approximately 1,500 SNFs from the 1995 base period. However, because this methodology relied on data from 1995, we proposed a new methodology based on updated data (as discussed below) to apply the offsets required for the exclusion of the blood clotting factors and items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act (referred to collectively as the blood clotting factor exclusion), as specified under the Consolidated Appropriations Act, 2021. As we noted in the proposed rule, we believe the use of the updated data will more accurately capture the actual cost of these factors, as using updated utilization data would reflect new types of blood clotting factors introduced in recent years and changes in utilization patterns of blood clotting factors since 1995.

The methodology for calculating the blood clotting factor exclusion offset as set forth in the proposed rule consists of five steps. In the first step, we begin with the total number of SNF utilization days for beneficiaries who have any amount of blood clotting factor (BCF) use in FY 2020. While we recognize the potential effects of the PHE for COVID–19 on SNF utilization during 2020, we believe we should use FY 2020 data because it is the most recent data available, and thus would best reflect the latest types of blood clotting factors and the most recent changes in utilization patterns; also, the FY 2020 data is the only data available that reflects utilization under the PDPM model rather than the RUG–IV model. However, in light of the potential impact of the PHE for COVID–19 on SNF utilization, particularly as it relates to those patients admitted with COVID–19 or whose stays utilized a PHE-related waiver (for example, the waiver which removes the requirement for a three-day prior inpatient hospital stay in order to receive SNF Part A coverage), we believe it is appropriate to use a subset of the full FY 2020 SNF population which excludes patients diagnosed with COVID–19 and those stays which utilized a PHE-related waiver. We discuss this concept in more detail in relation to the recalibration of the PDPM parity adjustment, discussed in section VI.C. of this final rule. As further explained below, we would note that using this subset population has very little impact on the result of the methodology described below. Throughout the discussion below, the term ''SNF beneficiary'' refers to beneficiaries in the FY 2020 subset population described above.

Since BCF use has historically been subject to SNF consolidated billing and its usage cannot be observed on billed SNF claims, this methodology resorts to claims from other settings to approximate BCF utilization in SNFs. Specifically, BCF use as well as items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act are identified by checking if any of the Healthcare Common Procedure Coding System (HCPCS) codes listed in the Act, including J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211, are recorded on outpatient claims, which are claims submitted by institutional outpatient providers (such as a hospital outpatient department), or carrier claims, which are fee-for-service claims submitted by professional practitioners, such as physicians, physician assistants, clinical social workers, and nurse practitioners, and by some organizational providers, such as free-standing facilities. A SNF beneficiary with any BCF use is defined as a SNF beneficiary with at least one matched outpatient or carrier claim for blood clotting factors in FY 2020. To calculate the number of SNF utilization days for beneficiaries who have any amount of BCF use in FY 2020, we sum up the corresponding SNF utilization days of SNF beneficiaries with BCF use in FY 2020 (84 beneficiaries), which is 3,317 total utilization days.

In the second step, we estimate the BCF payment per day per SNF beneficiary with any BCF use in FY 2020, which would include payment for the BCFs and items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act. There are no direct payment data to track BCF use in SNFs since BCF use currently is bundled within the Part A per diem payment. Therefore, we rely on payment in outpatient and carrier claims as a proxy for this step. Instead of calculating BCF payment per day for SNF beneficiaries in a SNF stay, we estimate the BCF payment per day for SNF beneficiaries outside of their SNF and inpatient stays, under the assumption that BCF payment per day for SNF beneficiaries is similar during and outside of SNF stays. Outpatient or carrier claims for BCF use that overlap with a SNF stay or an inpatient stay of a SNF beneficiary are excluded to ensure that BCF-related payment is fully captured in Part B claims instead of partially paid through Part A. Overlapping claims are identified when the outpatient claim ''From'' date or the carrier claim expense date fall within a SNF or inpatient stay's admission and discharge date window. The total BCF payment for SNF beneficiaries' BCF use

observed through Part B claims in FY 2020 was $4,843,551. Next, to determine the corresponding utilizations days for SNF beneficiaries' BCF use, we need to carve out their utilization days in a SNF or inpatient setting for these target beneficiaries. We first determine the total SNF and inpatient utilization days for these beneficiaries in FY 2020, which totals 5,408. Next, we determine the total days that the beneficiaries with BCF use were not in a SNF or inpatient stay, which is 365 (for days in the year) multiplied by the number of SNF beneficiaries with BCF use (84), less the total SNF and inpatient utilization days for these beneficiaries (5,408), which is 20,142. Finally, we estimated the BCF payment per day, which is the total BCF payment observed in outpatient and carrier claims ($4,843,551) divided by the total days the beneficiaries were not in a SNF or inpatient setting (20,142). Thus, we calculate the BCF payment per day per SNF beneficiary to be $240.

In the third step, we calculate the percentage of SNF payment associated with BCF usage. We multiply the estimated BCF payment per day ($240 as determined in step 2) by the total SNF utilization days for SNF beneficiaries with BCF use in FY 2020 (3,317 as determined in step 1). This yields an estimated BCF payment for SNF beneficiaries in the study population of $797,640. Next, we divide this by the total SNF payment for the study population during FY 2020 ($22,636,345,868) to yield the percentage of SNF payment associated with BCF use, which we estimate to be 0.00352 percent.

In the fourth step, we calculate the urban and rural base rate reductions, by multiplying the proposed FY 2022 urban/rural base rates by the percentage of SNF payment associated with clotting factor use determined in step 3 (0.00352 percent). In the case of the proposed urban base rate of $434.95, this yields an urban base rate deduction of $0.02, which we would apply as a $0.01 reduction to the proposed FY 2022 NTA base rate and a $0.01 reduction to the proposed FY 2022 nursing base rate. In the case of the proposed rural base rate of $450.37, this yields a rural base rate deduction of $0.02, which we would apply as a $0.01 reduction to the proposed FY 2022 NTA base rates and a $0.01 reduction to the proposed FY 2022 nursing base rate. We would apply the reduction to the NTA and nursing base rates because BCF is a type of NTA and nursing resources are required to furnish this medication.

In step five, for purposes of impact analysis, we calculate the budget impact of the base rate reductions to be $782,785. We estimate the budget impact by multiplying the total FY2022 SNF baseline ($34,211,000,000) by the percentage of SNF payment for clotting factor (0.00352 percent). This results in a total reduction in SNF spending of $1.2 million. To compare the result of this methodology to that which would have resulted from using the full FY 2020 SNF population, we note that if we had used the full FY 2020 SNF population, the resultant impact would be a reduction in SNF spending of $1.5 million, which represents 0.004551 percent of total payments made under the SNF PPS. Given that these figures are so close as to result in the same two cent reduction in the FY 2022 SNF PPS unadjusted per diem rates, and given the reasons for using the subset population discussed in section VI.C. of this final rule, we believe it is appropriate to use this subset population as the basis for the calculations described throughout this section.

We apply these rate reductions to the NTA and nursing components of the unadjusted Federal urban and rural per diem rate as shown in Tables 4 and 5.

Table 3 displays the methodology and figures used to calculate these rate reductions.

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TABLE 3: Estimation of Blood Clotting Factor on Base Rate Reduction

Step 1: SNF Utilization Days of Benes with Any BCF Use	
FY2020 # SNF Benes with Any BCF Use	84
FY2020 Total SNF Util Days for Benes with Any BCF Use	3,317
Step 2: Clotting Factor Payment per Day per SNF Bene with Any BCF Use	
FY2020 Total Part B Clotting Factor Payment for Benes with Any BCF Use Outside of SNF or Inpatient Stay	$4,843,551
FY2020 Total SNF and Inpatient Util Days for Benes with Any BCF Use	5,408
FY2020 Total Days Not in SNF or Inpatient Stay for Benes with Any BCF Use	20,142
FY2020 Clotting Factor Payment per Day	$240
Step 3: % of SNF Payment Associated with Clotting Factor Use	
FY2020 Estimated Clotting Factor Payment in SNF	$797,640
FY2020 Total SNF Payment	$22,636,345,868
% of SNF Payment Associated with Clotting Factor Use	0.00352%
Step 4: Calculate Urban and Rural Base Rate Reductions	
FY2022 Urban Base Rate	$434.95
FY2022 Urban Base Rate Reduction for Clotting Factor Use	$0.02
FY2022 Rural Base Rate	$450.37
FY2022 Rural Base Rate Reduction for Clotting Factor Use	$0.02
Step 4: Impact Analysis	
FY2022 SNF Baseline	$34,211,000,000
Budget Impact of Base Rate Reductions	$782,785

The comments we received on the proposed methodology to adjust the SNF PPS base rates in response to the recent blood clotting factor exclusion, along with our responses, appear below.

Comment: Several commenters noted support for the proposed methodology for adjusting the base rates to remove the costs associated with Blood Clotting Factor (BCF)-related services from the Part A consolidated billing per diem payment that resulted in a proposed 0.00352 percent adjustment. A commenter noted that this methodology is preferable to the alternative methodology that would result in a 0.004551 percent adjustment.

Response: We thank the commenters for their support. Accordingly, we are finalizing, as proposed, the methodology for reducing the base rates to remove the costs associated with Blood Clotting Factor (BCF)-related services.

Tables 4 and 5 reflect the updated unadjusted Federal rates for FY 2022, prior to adjustment for case-mix. The rates in Tables 4 and 5 include the reductions calculated in Table 3 for blood clotting factor use.

TABLE 4: FY 2022 Unadjusted Federal Rate Per Diem—URBAN

Rate Component	PT	OT	SLP	Nursing	NTA	Non-Case-Mix
Per Diem Amount	$62.82	$58.48	$23.45	$109.51	$82.62	$98.07

TABLE 5: FY 2022 Unadjusted Federal Rate Per Diem—RURAL

Rate Component	PT	OT	SLP	Nursing	NTA	Non-Case-Mix
Per Diem Amount	$71.61	$65.77	$29.55	$104.63	$78.93	$99.88

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C. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the Federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the FY 2019 final rule (83 FR 39162, August 8, 2018), we finalized a new case-mix classification model, the PDPM, which took effect beginning October 1, 2019. The previous RUG–IV model classified most patients into a therapy payment group and primarily used the volume of therapy services provided to the patient as the basis for payment classification, thus creating an incentive for SNFs to furnish therapy regardless of the individual patient's unique characteristics, goals, or needs. PDPM eliminates this incentive and improves the overall accuracy and appropriateness of SNF payments by classifying patients into payment groups based on specific, data-driven patient characteristics, while simultaneously reducing the administrative burden on SNFs.

As we noted in the FY 2021 SNF PPS final rule (85 FR 47600), we continue to monitor the impact of PDPM implementation on patient outcomes and program outlays. We hope to release information in the future that relates to these issues, though we provide some of this information in section VI.C. of this final rule. We also continue to monitor the impact of PDPM implementation as it relates to our intention to ensure that PDPM is implemented in a budget neutral manner, as discussed in the FY 2020 SNF PPS final rule (84 FR 38734). In section VI.C. of this final rule, we discuss the methodology to recalibrate the PDPM parity adjustment as appropriate to ensure budget neutrality, as we did after the implementation of RUG–IV in FY 2011.

The PDPM uses clinical data from the MDS to assign case-mix classifiers to each patient that are then used to calculate a per diem payment under the SNF PPS, consistent with the provisions of section 1888(e)(4)(G)(i) of the Act. As discussed in section V.A. of this final rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the timeframes for MDS completion in our Resident Assessment Instrument (RAI) Manual. As we have stated in prior rules, for an MDS to be considered valid for use in determining payment, the MDS assessment should be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS website at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.*

Under section 1888(e)(4)(H) of the Act, each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The FY 2022 payment rates set forth in this final rule reflect the use of the PDPM case-mix classification system from October 1, 2021, through September 30, 2022. The case-mix adjusted PDPM payment rates for FY 2022 are listed separately for urban and rural SNFs, in Tables 6 and 7 with corresponding case-mix values.

Given the differences between the previous RUG–IV model and PDPM in terms of patient classification and billing, it was important that the format of Tables 6 and 7 reflect these differences. More specifically, under both RUG–IV and PDPM, providers use a Health Insurance Prospective Payment System (HIPPS) code on a claim to bill for covered SNF services. Under RUG–IV, the HIPPS code included the three-character RUG–IV group into which the patient classified as well as a two-character assessment indicator code that represented the assessment used to generate this code. Under PDPM, while providers still use a HIPPS code, the characters in that code represent different things. For example, the first character represents the PT and OT group into which the patient classifies. If the patient is classified into the PT and OT group ''TA'', then the first character in the patient's HIPPS code would be an A. Similarly, if the patient is classified into the SLP group ''SB'', then the second character in the patient's HIPPS code would be a B. The third character represents the Nursing group into which the patient classifies. The fourth character represents the NTA group into which the patient classifies. Finally, the fifth character represents the assessment used to generate the HIPPS code.

Tables 6 and 7 reflect the PDPM's structure. Accordingly, Column 1 of Tables 6 and 7 represents the character in the HIPPS code associated with a given PDPM component. Columns 2 and 3 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant PT group. Columns 4 and 5 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant OT group. Columns 6 and 7 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant SLP group. Column 8 provides the nursing case-mix group (CMG) that is connected with a given PDPM HIPPS character. For example, if the patient qualified for the nursing group CBC1, then the third character in the patient's HIPPS code would be a ''P.'' Columns 9 and 10 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant nursing group. Finally, columns 11 and 12 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant NTA group.

Tables 6 and 7 do not reflect adjustments which may be made to the SNF PPS rates as a result of the SNF VBP Program, discussed in section IV.D. of this final rule, or other adjustments, such as the variable per diem adjustment. Further, in the past, we used the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos, 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. As discussed in the FY 2021 SNF PPS final rule (85 FR 47594), we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) to identify a facility's urban or rural status effective beginning with FY 2021.

TABLE 6: PDPM Case-Mix Adjusted Federal Rates and Associated Indexes—URBAN

PDPM Group	PT CMI	PT Rate	OT CMI	OT Rate	SLP CMI	SLP Rate	Nursing CMG	Nursing CMI	Nursing Rate	NTA CMI	NTA Rate
A	1.53	$96.11	1.49	$87.14	0.68	$15.95	ES3	4.06	$444.61	3.24	$267.69
B	1.70	$106.79	1.63	$95.32	1.82	$42.68	ES2	3.07	$336.20	2.53	$209.03
C	1.88	$118.10	1.69	$98.83	2.67	$62.61	ES1	2.93	$320.86	1.84	$152.02
D	1.92	$120.61	1.53	$89.47	1.46	$34.24	HDE2	2.40	$262.82	1.33	$109.88
E	1.42	$89.20	1.41	$82.46	2.34	$54.87	HDE1	1.99	$217.92	0.96	$79.32
F	1.61	$101.14	1.60	$93.57	2.98	$69.88	HBC2	2.24	$245.30	0.72	$59.49
G	1.67	$104.91	1.64	$95.91	2.04	$47.84	HBC1	1.86	$203.69	-	-
H	1.16	$72.87	1.15	$67.25	2.86	$67.07	LDE2	2.08	$227.78	-	-
I	1.13	$70.99	1.18	$69.01	3.53	$82.78	LDE1	1.73	$189.45	-	-
J	1.42	$89.20	1.45	$84.80	2.99	$70.12	LBC2	1.72	$188.36	-	-
K	1.52	$95.49	1.54	$90.06	3.7	$86.77	LBC1	1.43	$156.60	-	-
L	1.09	$68.47	1.11	$64.91	4.21	$98.72	CDE2	1.87	$204.78	-	-
M	1.27	$79.78	1.30	$76.02	-	-	CDE1	1.62	$177.41	-	-
N	1.48	$92.97	1.50	$87.72	-	-	CBC2	1.55	$169.74	-	-
O	1.55	$97.37	1.55	$90.64	-	-	CA2	1.09	$119.37	-	-
P	1.08	$67.85	1.09	$63.74	-	-	CBC1	1.34	$146.74	-	-
Q	-	-	-	-	-	-	CA1	0.94	$102.94	-	-
R	-	-	-	-	-	-	BAB2	1.04	$113.89	-	-
S	-	-	-	-	-	-	BAB1	0.99	$108.41	-	-
T	-	-	-	-	-	-	PDE2	1.57	$171.93	-	-
U	-	-	-	-	-	-	PDE1	1.47	$160.98	-	-
V	-	-	-	-	-	-	PBC2	1.22	$133.60	-	-
W	-	-	-	-	-	-	PA2	0.71	$77.75	-	-
X	-	-	-	-	-	-	PBC1	1.13	$123.75	-	-
Y	-	-	-	-	-	-	PA1	0.66	$72.28	-	-

TABLE 7: PDPM Case-Mix Adjusted Federal Rates and Associated Indexes—RURAL

PDPM Group	PT CMI	PT Rate	OT CMI	OT Rate	SLP CMI	SLP Rate	Nursing CMG	Nursing CMI	Nursing Rate	NTA CMI	NTA Rate
A	1.53	$109.56	1.49	$98.00	0.68	$20.09	ES3	4.06	$424.80	3.24	$255.73
B	1.70	$121.74	1.63	$107.21	1.82	$53.78	ES2	3.07	$321.21	2.53	$199.69
C	1.88	$134.63	1.69	$111.15	2.67	$78.90	ES1	2.93	$306.57	1.84	$145.23
D	1.92	$137.49	1.53	$100.63	1.46	$43.14	HDE2	2.40	$251.11	1.33	$104.98
E	1.42	$101.69	1.41	$92.74	2.34	$69.15	HDE1	1.99	$208.21	0.96	$75.77
F	1.61	$115.29	1.60	$105.23	2.98	$88.06	HBC2	2.24	$234.37	0.72	$56.83
G	1.67	$119.59	1.64	$107.86	2.04	$60.28	HBC1	1.86	$194.61	-	-
H	1.16	$83.07	1.15	$75.64	2.86	$84.51	LDE2	2.08	$217.63	-	-
I	1.13	$80.92	1.18	$77.61	3.53	$104.31	LDE1	1.73	$181.01	-	-
J	1.42	$101.69	1.45	$95.37	2.99	$88.35	LBC2	1.72	$179.96	-	-
K	1.52	$108.85	1.54	$101.29	3.7	$109.34	LBC1	1.43	$149.62	-	-
L	1.09	$78.05	1.11	$73.00	4.21	$124.41	CDE2	1.87	$195.66	-	-
M	1.27	$90.94	1.30	$85.50	-	-	CDE1	1.62	$169.50	-	-
N	1.48	$105.98	1.50	$98.66	-	-	CBC2	1.55	$162.18	-	-
O	1.55	$111.00	1.55	$101.94	-	-	CA2	1.09	$114.05	-	-
P	1.08	$77.34	1.09	$71.69	-	-	CBC1	1.34	$140.20	-	-
Q	-	-	-	-	-	-	CA1	0.94	$98.35	-	-
R	-	-	-	-	-	-	BAB2	1.04	$108.82	-	-
S	-	-	-	-	-	-	BAB1	0.99	$103.58	-	-
T	-	-	-	-	-	-	PDE2	1.57	$164.27	-	-
U	-	-	-	-	-	-	PDE1	1.47	$153.81	-	-
V	-	-	-	-	-	-	PBC2	1.22	$127.65	-	-
W	-	-	-	-	-	-	PA2	0.71	$74.29	-	-
X	-	-	-	-	-	-	PBC1	1.13	$118.23	-	-
Y	-	-	-	-	-	-	PA1	0.66	$69.06	-	-

D. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the Federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We continue this practice for FY 2022, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data under the inpatient prospective payment system (IPPS) also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. As in previous years, we would continue to use the pre-reclassified IPPS hospital wage data, without applying the occupational mix, rural floor, or outmigration adjustment, as the basis for the SNF PPS wage index. For FY 2022, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2017 and before October 1, 2018 (FY 2018 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted December 21, 2000) authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF PPS wage index that is based on wage data from nursing homes. However, to date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of the data. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the IPPS wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. In addition, adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS given that there are nearly five times as many SNFs as there are inpatient hospitals. Therefore, while we continue to believe that the development of such an audit process could improve SNF cost reports in such a manner as to permit us to establish a SNF-specific wage index, we do not believe this undertaking is feasible at this time.

In the proposed rule, we proposed to continue using the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2022 SNF PPS wage index. For rural geographic areas that do not have hospitals and, therefore, lack hospital wage data on which to base an area wage adjustment, we proposed to continue using the average wage index from all contiguous

Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2022, there are no rural geographic areas that do not have hospitals, and thus, this methodology will not be applied. For rural Puerto Rico, we proposed not to apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we would continue using the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we proposed that we would use the average wage indexes of all of the urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2022, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA.

The wage index applicable to FY 2022 is set forth in Tables A and B available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas. In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), after the expiration of this 1-year transition on September 30, 2006, we used the full CBSA-based wage index values.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). Subsequently, on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided minor updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were 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 and were adopted under the SNF PPS in the FY 2017 SNF PPS final rule (81 FR 51983, August 5, 2016). In addition, on August 15, 2017, OMB issued Bulletin No. 17–01 which announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300) which was adopted in the SNF PPS final rule for FY 2019 (83 FR 39173, August 8, 2018).

As discussed in the FY 2021 SNF PPS final rule (85 FR 47594), we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) beginning October 1, 2020, including a 1-year transition for FY 2021 under which we applied a 5 percent cap on any decrease in a hospital's wage index compared to its wage index for the prior fiscal year (FY 2020). The updated OMB delineations more accurately reflect the contemporary urban and rural nature of areas across the country, and the use of such delineations allows us to determine more accurately the appropriate wage index and rate tables to apply under the SNF PPS.

As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), this and all subsequent SNF PPS rules and notices are considered to incorporate any updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index. We note that on March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the updates (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). In the FY 2021 SNF PPS final rule (85 FR 47611), we stated that we intended to propose any updates from OMB Bulletin No. 20–01 in the FY 2022 SNF PPS proposed rule. After reviewing OMB Bulletin No. 20–01, we have determined that the changes in OMB Bulletin 20–01 encompassed delineation changes that do not impact the CBSA-based labor market area delineations adopted in FY 2021. Therefore, while we proposed to adopt the updates set forth in OMB Bulletin No. 20–01 consistent with our longstanding policy of adopting OMB delineation updates, we noted that specific wage index updates would not be necessary for FY 2022 as a result of adopting these OMB updates.

The proposed wage index applicable to FY 2022 is set forth in Tables A and B and is available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Once calculated, we would apply the wage index adjustment to the labor-related portion of the Federal rate. Each year, we calculate a revised labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we finalized a proposal to revise the labor-related share to reflect the relative importance of the 2014-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses. Effective beginning FY 2022, as discussed in section VI.A.4. of this final rule, for FY 2022, we are rebasing and revising the labor-related share to reflect the relative importance of the 2018-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional fees: Labor-related; Administrative and Facilities Support services; Installation, Maintenance, and Repair services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses. The methodology for calculating the labor-related portion for FY 2022 is discussed in section VI.A. of this final rule.

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related

portion of the total costs after taking into account historical and projected price changes between the base year and FY 2022. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2022 than the base year weights from the SNF market basket. We calculate the labor-related relative importance for FY 2022 in four steps. First, we compute the FY 2022 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2022 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2022 relative importance for each cost category by multiplying this ratio by the base year (2018) weight. Finally, we add the FY 2022 relative importance for each of the labor-related cost categories (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related services; and a portion of Capital-Related expenses) to produce the FY 2022 labor-related relative importance.

For the proposed rule, the labor-related share for FY 2022 was based on IGI's fourth quarter 2020 forecast of the proposed 2018-based SNF market basket with historical data through third quarter 2020. For this final rule, we based the labor-related share for FY 2022 on IGI's second quarter 2021 forecast, with historical data through the first quarter 2021. Table 8 summarizes the labor-related share for FY 2022, based on IGI's second quarter 2021 forecast of the 2018-based SNF market basket with historical data through first quarter 2021, compared to the labor-related share that was used for the FY 2021 SNF PPS final rule.

TABLE 8: Labor-Related Relative Importance, FY 2021 and FY 2022

	Relative importance, labor-related share, FY 2021 20:2 forecast[1]	Relative importance, labor-related share, FY 2022 21:2 forecast[2]
Wages and salaries	51.1	51.4
Employee benefits	9.9	9.5
Professional fees: Labor-related	3.7	3.5
Administrative & facilities support services	0.5	0.6
Installation, maintenance & repair services	0.6	0.4
All other: Labor-related services	2.6	2.0
Capital-related (.391)	2.9	3.0
Total	71.3	70.4

[1] Published in the **Federal Register** (85 FR 47605); based on the second quarter 2020 IHS Global Inc. forecast of the 2014-based SNF market basket, with historical data through first quarter 2020.
[2] Based on the second quarter 2021 IHS Global Inc. forecast of the 2018-based SNF market basket, with historical data through first quarter 2021.

To calculate the labor portion of the case-mix adjusted per diem rate, we would multiply the total case-mix adjusted per diem rate, which is the sum of all five case-mix adjusted components into which a patient classifies, and the non-case-mix component rate, by the FY 2022 labor-related share percentage provided in Table 8. The remaining portion of the rate would be the non-labor portion. Under the previous RUG–IV model, we included tables which provided the case-mix adjusted RUG–IV rates, by RUG–IV group, broken out by total rate, labor portion and non-labor portion, such as Table 9 of the FY 2019 SNF PPS final rule (83 FR 39175). However, as we discussed in the FY 2020 final rule (84 FR 38738), under PDPM, as the total rate is calculated as a combination of six different component rates, five of which are case-mix adjusted, and given the sheer volume of possible combinations of these five case-mix adjusted components, it is not feasible to provide tables similar to those that existed in the prior rulemaking.

Therefore, to aid stakeholders in understanding the effect of the wage index on the calculation of the SNF per diem rate, we have included a hypothetical rate calculation in Table 9.

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2022 (Federal rates effective October 1, 2021), we apply an adjustment to fulfill the budget neutrality requirement. We meet this requirement by multiplying each of the components of the unadjusted Federal rates by a budget neutrality factor, equal to the ratio of the weighted average wage adjustment factor for FY 2021 to the weighted average wage adjustment factor for FY 2022. For this calculation, we would use the same FY 2020 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor portion of the rate component multiplied by the wage index plus the non-labor portion of the rate component. The proposed budget neutrality factor for FY 2022 as set forth in the proposed rule was 0.9999.

In the proposed rule, we noted that if more recent data become available (for example, revised wage data), we would use such data, as appropriate, to determine the wage index budget neutrality factor in the SNF PPS final rule. Since the proposed rule, we have updated the weighted average wage

adjustment factor for FY 2022. Based on this updated information, the budget neutrality factor for FY 2022 is 1.0006.

The following is a summary of the public comments received on the proposed revisions to the Wage Index Adjustment and our responses:

Comment: Several commenters recommended that we consider creating a SNF-specific wage index utilizing the SNF cost report, as opposed to continuing to rely on hospital data as the basis for the SNF wage index. Commenters requested the SNF wage data analysis and access to needed hospital and SNF cost report wage data to conduct their own analysis towards assisting us in refining the current SNF wage index methodology. Additionally, one commenter requested to meet with CMS to discuss these ideas, while another commenter would like to provide more feedback.

Response: We appreciate the commenter's suggestion as to the development of a SNF specific wage index. However, to date, the development of a SNF-specific wage index has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data. We note that, consistent with the preceding discussion in this final rule as well as our previous responses to these recurring SNF-specific wage index comments (most recently published in the FY 2019 SNF PPS final rule (83 FR 39172 through 39173)), developing such a wage index would require a resource-intensive audit process similar to that used for IPPS hospital data, to improve the quality of the SNF cost report data in order for it to be used as part of this analysis. We also discussed in the FY 2019 SNF PPS why utilizing concepts such as trimming methods, BLS data, occupational mix, Payroll Based Journal, and rural floor are unfeasible or not applicable to SNF policy. We continue to believe that in the absence of the appropriate SNF-specific wage data, using the pre-reclassified, pre-rural floor hospital inpatient wage data (without the occupational mix adjustment) is appropriate and reasonable for the SNF PPS.

Regarding the request for data, we will consider the comments and examine what data could be released that would assist stakeholders in understanding both the volatility of the SNF wage data and the issues with using this data to develop a SNF-specific wage index. As always, we encourage and welcome dialogue with stakeholders regarding this, or any other, issues related to SNF payments under Medicare.

Comment: We received several comments that were outside the scope of the FY 2022 SNF PPS proposed rule. Specifically, commenters appreciated that, in the SNF PPS final rule for FY 2021, CMS recognized the need for a transitional policy in the form of a 5 percent cap on any decease in a SNF's wage index in adopting the OMB delineations updated in OMB Bulletin 18–04. However, these commenters also expressed that a 1-year cap is not sufficient to offset the enormous cuts scheduled for FY 2022, thus requesting an extension to the 5 percent cap transition.

Response: We thank the commenters for bringing this issue to our attention. We note that at times when changes to the wage index occur, those changes may result in large and potentially unpredictable impacts on Medicare payments that impact providers. These changes may arise from changes to wage index areas due to updates related to decennial census data, changes to wage index areas due to updates related to revised OMB delineations. While we consider how best to address these potential scenarios in a consistent and thoughtful manner, we reiterate that our policy principles with regard to the wage index are to use the most updated data and information available and provide that data and information, as well as any approaches to addressing these potential scenarios, through notice and comment rulemaking.

After considering the comments received, for the reasons set forth in this final rule and in the FY 2022 SNF PPS proposed rule, we are finalizing our proposal to adopt the revised OMB delineations contained in OMB Bulletin 18–04 as proposed, without modification.

E. SNF Value-Based Purchasing Program

Beginning with payment for services furnished on October 1, 2018, section 1888(h) of the Act requires the Secretary to reduce the adjusted Federal per diem rate determined under section 1888(e)(4)(G) of the Act otherwise applicable to a SNF for services furnished during a fiscal year by 2 percent, and to adjust the resulting rate for a SNF by the value-based incentive payment amount earned by the SNF based on the SNF's performance score for that fiscal year under the SNF VBP Program. To implement these requirements, we finalized in the FY 2019 SNF PPS final rule the addition of § 413.337(f) to our regulations (83 FR 39178).

Please see section VIII. of this final rule for a further discussion of our policies for the SNF VBP Program.

F. Adjusted Rate Computation Example

Tables 9, 10, and 11 provide examples generally illustrating payment calculations during FY 2022 under PDPM for a hypothetical 30-day SNF stay, involving the hypothetical SNF XYZ, located in Frederick, MD (Urban CBSA 23244), for a hypothetical patient who is classified into such groups that the patient's HIPPS code is NHNC1. Table 9 shows the adjustments made to the Federal per diem rates (prior to application of any adjustments under the SNF VBP Program as discussed previously) to compute the provider's case-mix adjusted per diem rate for FY 2022, based on the patient's PDPM classification, as well as how the variable per diem (VPD) adjustment factor affects calculation of the per diem rate for a given day of the stay. Table 10 shows the adjustments made to the case-mix adjusted per diem rate from Table 9 to account for the provider's wage index. The wage index used in this example is based on the FY 2022 SNF PPS wage index that appears in Table A available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.* Finally, Table 11 provides the case-mix and wage index adjusted per-diem rate for this patient for each day of the 30-day stay, as well as the total payment for this stay. Table 11 also includes the VPD adjustment factors for each day of the patient's stay, to clarify why the patient's per diem rate changes for certain days of the stay. As illustrated in Table 9, SNF XYZ's total PPS payment for this particular patient's stay would equal $20,532.52.

TABLE 9: PDPM Case-Mix Adjusted Rate Computation Example

Per Diem Rate Calculation				
Component	**Component Group**	**Component Rate**	**VPD Adjustment Factor**	**VPD Adj. Rate**
PT	N	$92.97	1.00	$92.97
OT	N	$87.72	1.00	$87.72
SLP	H	$67.07	1.00	$67.07
Nursing	N	$169.74	1.00	$169.74
NTA	C	$152.02	3.00	$456.06
Non-Case-Mix	-	$98.07	-	$98.07
Total PDPM Case-Mix Adj. Per Diem				$971.63

TABLE 10: Wage Index Adjusted Rate Computation Example

PDPM Wage Index Adjustment Calculation						
HIPPS Code	**PDPM Case-Mix Adjusted Per Diem**	**Labor Portion**	**Wage Index**	**Wage Index Adjusted Rate**	**Non-Labor Portion**	**Total Case Mix and Wage Index Adj. Rate**
NHNC1	$971.63	$684.03	0.9755	$667.27	$287.60	$954.87

TABLE 11: Adjusted Rate Computation Example

Day of Stay	NTA VPD Adjustment Factor	PT/OT VPD Adjustment Factor	Case Mix and Wage Index Adjusted Per Diem Rate
1	3.0	1.0	$954.87
2	3.0	1.0	$954.87
3	3.0	1.0	$954.87
4	1.0	1.0	$656.08
5	1.0	1.0	$656.08
6	1.0	1.0	$656.08
7	1.0	1.0	$656.08
8	1.0	1.0	$656.08
9	1.0	1.0	$656.08
10	1.0	1.0	$656.08
11	1.0	1.0	$656.08
12	1.0	1.0	$656.08
13	1.0	1.0	$656.08
14	1.0	1.0	$656.08
15	1.0	1.0	$656.08
16	1.0	1.0	$656.08
17	1.0	1.0	$656.08
18	1.0	1.0	$656.08
19	1.0	1.0	$656.08
20	1.0	1.0	$656.08
21	1.0	0.98	$652.52
22	1.0	0.98	$652.52
23	1.0	0.98	$652.52
24	1.0	0.98	$652.52
25	1.0	0.98	$652.52
26	1.0	0.98	$652.52
27	1.0	0.98	$652.52
28	1.0	0.96	$648.97
29	1.0	0.96	$648.97
30	1.0	0.96	$648.97
Total Payment			$20,532.52

V. Additional Aspects of the SNF PPS

A. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section IV.C. of this final rule. This approach includes an administrative presumption that utilizes a beneficiary's correct assignment, at the outset of the SNF stay, of one of the case-mix classifiers designated for this purpose to assist in making certain SNF level of care determinations.

In accordance with § 413.345, we include in each update of the Federal payment rates in the **Federal Register** a discussion of the resident classification system that provides the basis for case-mix adjustment. We also designate those specific classifiers under the case-mix classification system that represent the required SNF level of care, as provided in 42 CFR 409.30. This designation reflects an administrative presumption that those beneficiaries who are correctly assigned one of the designated case-mix classifiers on the initial Medicare assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) for that assessment.

A beneficiary who does not qualify for the presumption is not automatically classified as either meeting or not meeting the level of care definition, but instead receives an individual determination on this point using the existing administrative criteria. This presumption recognizes the strong likelihood that those beneficiaries who are correctly assigned one of the designated case-mix classifiers during the immediate post-hospital period would require a covered level of care, which would be less likely for other beneficiaries.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. The FY 2018 final rule (82 FR 36544) further specified that we would henceforth disseminate the standard description of the administrative presumption's designated groups via the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/*

index.html (where such designations appear in the paragraph entitled ''Case Mix Adjustment''), and would publish such designations in rulemaking only to the extent that we actually intend to propose changes in them. Under that approach, the set of case-mix classifiers designated for this purpose under PDPM was finalized in the FY 2019 SNF PPS final rule (83 FR 39253) and is posted on the SNF PPS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*), in the paragraph entitled ''Case Mix Adjustment.''

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that any services prompting the assignment of one of the designated case-mix classifiers (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations where the sole classifier that triggers the presumption is itself assigned through the receipt of services that are subsequently determined to be not reasonable and necessary. Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the ARD of the initial Medicare assessment.

B. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA 1997) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor (MAC) for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.* In particular, section 103 of the BBRA 1999 amended section 1888(e)(2)(A)(iii) of the Act by further excluding a number of individual high-cost, low probability services, identified by HCPCS codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA 1999 amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf.*

As explained in the FY 2001 proposed rule (65 FR 19232), the amendments enacted in section 103 of the BBRA 1999 not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary the authority to designate additional, individual services for exclusion within each of these four specified service categories. In the proposed rule for FY 2001, we also noted that the BBRA 1999 Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the individual services that this legislation targets for exclusion as high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment SNFs receive under the PPS. According to the conferees, section 103(a) of the BBRA 1999 is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. By contrast, the amendments enacted in section 103 of the BBRA 1999 do not designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and as is consistent with our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA 1999: They must fall within one of the four service categories specified in the BBRA 1999; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA 1999 Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice) (65 FR 46791).

Effective with items and services furnished on or after October 1, 2021, section 134 in Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) has established an additional category of excluded codes in section 1888(e)(2)(A)(iii)(VI) of the Act, for certain blood clotting factors for the treatment of patients with hemophilia and other bleeding disorders along with items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act. The specific factors, and items and services related to the furnishing of such factors, excluded under this provision are those identified, as of July 1, 2020, by HCPCS codes J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211. Like the provisions enacted in the BBRA 1999, new section 1888(e)(2)(A)(iii)(VI) of the Act gives the Secretary the authority to designate additional items and services for exclusion within the category of items and services described in that section. Section 1888(e)(4)(G)(iii) of the Act further requires that for any services that are unbundled from consolidated billing under section 1888(e)(2)(A)(iii) of the Act (and, thus, become qualified for separate payment under Part B), there must also be a corresponding proportional reduction made in aggregate SNF payments under Part A. Accordingly, using the methodology described in section III.B.6. of the proposed rule (see also section IV.B.6. of this final rule), we proposed to make a

proportional reduction of $0.02 in the unadjusted urban and rural rates to reflect these new exclusions, effective for items and services furnished on or after October 1, 2021.

In the proposed rule, we specifically invited public comments identifying HCPCS codes in any of these five service categories (chemotherapy items, chemotherapy administration services, radioisotope services, customized prosthetic devices, and blood clotting factors) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We noted that we may consider excluding a particular service if it meets our criteria for exclusion as specified previously. We requested that commenters identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

We noted that the original BBRA amendment and the Consolidated Appropriations Act, 2021 identified a set of excluded items and services by means of specifying individual HCPCS codes within the designated categories that were in effect as of a particular date (in the case of the BBRA 1999, July 1, 1999, and in the case of the Consolidated Appropriations Act, 2021, July 1, 2020), as subsequently modified by the Secretary. In addition, as noted above, the statute (section 1888(e)(2)(A)(iii)(II) through (VI) of the Act) gives the Secretary authority to identify additional items and services for exclusion within the categories of items and services described in the statute, which are also designated by HCPCS code. Designating the excluded services in this manner makes it possible for us to utilize program issuances as the vehicle for accomplishing routine updates to the excluded codes to reflect any minor revisions that might subsequently occur in the coding system itself, such as the assignment of a different code number to a service already designated as excluded, or the creation of a new code for a type of service that falls within one of the established exclusion categories and meets our criteria for exclusion (for example, J7212, ''factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram'', which became effective on January 1, 2021 and would fall in the blood clotting factor exclusion category).

Accordingly, we noted that in the event that we identify through the current rulemaking cycle any new services that would actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we would identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, October 1, 2021). By making any new exclusions in this manner, we could similarly accomplish routine future updates of these additional codes through the issuance of program instructions. The latest list of excluded codes can be found on the SNF Consolidated Billing website at *https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling.*

The following is a summary of the public comments received on the proposed revisions to Consolidated Billing and our responses:

Comment: Several commenters noted support for the exclusion of blood clotting factors (BCFs) and related items and services from consolidated billing. Commenters stated that the exclusion of these services from consolidated billing will increase care to beneficiaries with BCF disorders.

Response: We thank these commenters for their support. In accordance with this support and the legislative mandate to exclude BCFs from consolidated billing, we are finalizing the exclusion of BCFs as proposed.

Comment: One commenter suggested the addition of two HCPCS codes to the list of BCF-related services that are excluded from consolidated billing: J7204 (effective as of 7/1/2020) and J7212 (effective as of 1/1/2021). The commenter stated that these two J Codes also represent treatments for people with hemophilia—J7204 is for hemophilia A and J7212 is for hemophilia A or B with inhibitors.

Response: Upon review, we agree with the commenter and we have determined that HCPCS codes J7204 and J7212 should be excluded from consolidated billing. HCPCS code J7212 was not created until January 1, 2021, after Division CC, section 134 of the Consolidated Appropriations Act of 2001 (CAA) (Pub. L. 116–260, enacted on December 27, 2000) had been enacted, and the statutory exclusion designates codes that were identified as of July 1, 2020. HCPCS code J7204 was added on July 1, 2020; by contrast, the immediately adjacent codes of J7203 and J7205 had already been added much earlier, in 2019 and 2016, respectively. Accordingly, HCPCS codes J7204 and J7212 were not included in the statutory code range provided in the aforementioned legislation. However, as we stated in the proposed rule, section 1888(e)(2)(A)(iii) (VI) of the Act gives the Secretary authority to identify any additional blood clotting factors for exclusion. We further stated that we will utilize program issuances as the vehicle for making such routine updates to the list of excluded codes. In fact, we used J7212 as an example of a new code that we would designate through the issuance of program instructions. Accordingly, the new exclusions for HCPCS codes J7204 and J7212 will appear in a forthcoming consolidated billing update, with an effective date of October 1, 2021, the date that the statutory exclusion for BCFs takes effect.

Comment: One commenter requested us to consider a particular chemotherapy drug, RIABNI™ (rituximab-arrx), HCPCS code Q5123, that the commenter recommended as meeting the criteria for exclusion from consolidated billing. The commenter stated the drug meets the ''high-cost, low probability'' criteria for exclusion, represents a change in medical technology, and already has its own HCPCS code.

Response: We agree with the commenter and have determined that the drug described by HCPCS code Q5123 does qualify for exclusion. Its cost is comparable to other excluded chemotherapy drugs and it is rarely administered to SNF inpatients. Thus, it meets the ''high-cost, low probability'' standard in the SNF setting, as discussed in the BBRA 1999 Conf. Report. Furthermore, since it is a newly assigned code, the omission of this particular code from the original statutory code range would not indicate an intent for it to remain bundled. Accordingly, this new exclusion will appear in a forthcoming consolidated billing update.

Comment: One commenter encouraged CMS to exclude erythropoietin (EPO) when given for non-dialysis use. The commenter stated that currently CMS excludes erythropoietin (EPO) when given for dialysis, but not for other uses.

Response: We note that we have responded previously to comments regarding the use of EPO for non-dialysis purposes, including in the FY 2004 (68 FR 46059–62, August 4, 2003), FY 2006 (70 FR 45048–50, August 4, 2005), and FY 2008 (72 FR 43430–32, August 3, 2007) final rules. As we have noted previously in this final rule and in previous responses to comments on this issue in the past, section 1888(e)(2)(A)(iii) of the Act authorizes us to identify additional services for exclusion only within those particular service categories that it has designated for this purpose, and does not give us the authority to exclude other services which, though they may be related, fall

outside of the specified service categories themselves. Thus, while anti-emetics, for example, are commonly administered in conjunction with chemotherapy, they are not themselves inherently chemotherapeutic in nature and, consequently, do not fall within the excluded chemotherapy category designated in the section 1888(e)(2)(A)(iii)(II) of the Act. With regard to EPO, we additionally note that among the service categories that section 1888(e)(2)(A)(ii) of the Act already specifies as being excluded from SNF consolidated billing are items and services described in section 1861(s)(2)(O) of the Act—that is, EPO that is furnished to dialysis patients competent to use the such drug without medical or other supervision, and does not provide for coverage in any other, non-dialysis situations, such as chemotherapy. This means the exclusion under the consolidated billing provision for EPO falls within this scope.

Comment: One commenter reiterated the same set of comments that they had submitted in previous rulemaking cycles, noting the importance of continuing to exclude certain customized prosthetic devices from consolidated billing, and urging the exclusion of orthotics as well. The commenter also recommended the following four HCPCS codes for exclusion: L5000—Partial foot, shoe insert with longitudinal arch, toe filler; L5010—Partial foot, molded socket, ankle height, with toe filler; L5020—Partial foot, molded socket, tibial tubercle height, with toe filler; and L5987—All lower extremity prosthesis, shank foot system with vertical loading pylon.

Response: We refer to the previous discussions in the FY 2018 SNF PPS final rule (82 FR 36547) and FY 2017 SNF PPS final rule (81 FR 51986, August 5, 2016) regarding our decision not to adopt the recommendations for excluding orthotics as a class along with prosthetic codes L5010, L5020, and L5987. As we explained, it is our longstanding position that if a particular prosthetic code was already in existence as of the BBRA enactment date but was not designated in the BBRA for exclusion, this meant that it was intended to remain within the SNF PPS bundle. This would apply to all four of the prosthetic codes (L5000, L5010, L5020, and L5987) cited in the current comment.

Comment: One commenter encouraged CMS to address whether monoclonal antibody infusions for treatment of COVID–19 will be excluded from consolidated billing after the end of the COVID–19 PHE, to continue efforts to combat the infection in facilities.

Response: We appreciate the commenter's concern. However, as previously described in this rule, section 1888(e)(2)(A) of the Act authorizes us to identify additional services for exclusion from the consolidated billing requirements only within those particular service categories that it has designated for this purpose, and does not give us the authority to exclude other services which fall outside of the specified service categories themselves. Monoclonal antibody infusions do not fall within one of the specified service categories.

C. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, SNF-level services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this final rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. As discussed in the FY 2019 SNF PPS final rule (83 FR 39235), revisions were made to the swing bed assessment to support implementation of PDPM, effective October 1, 2019. A discussion of the assessment schedule and the MDS effective beginning FY 2020 appears in the FY 2019 SNF PPS final rule (83 FR 39229 through 39237). The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html.*

D. Revisions to the Regulation Text

In the proposed rule, we proposed to make certain revisions in the regulation text itself. Specifically, we proposed to redesignate current 42 CFR 411.15(p)(2)(xvii) and 489.20(s)(17) to §§ 411.15(p)(2)(xviii) and 489.20(s)(18), respectively, and to update the regulation text at §§ 411.15(p)(2)(xvii) and 489.20(s)(17) to reflect the recently-enacted exclusion from SNF consolidated billing at section 1888(e)(2)(A)(iii)(VI) of the Act effective for items and services furnished on or after October 1, 2021. Specifically, proposed revised §§ 411.15(p)(2)(xvii) and 489.20(s)(17) would reflect the exclusion of certain blood clotting factors for the treatment of patients with hemophilia and other bleeding disorders (identified by designated HCPCS codes in effect as of July 1, 2020, as subsequently modified by CMS), and items and services related to the furnishing of such factors, and would allow for the exclusion of any additional blood clotting factors identified by CMS and items and services related to the furnishing of such factors. In addition, we proposed to make conforming changes to the regulation text at §§ 411.15(p)(2)(xiii) through (xvi) and 489.20(s)(13) through (16) to reflect the authority that has always existed for CMS to make updates to the list of excluded codes as provided in section 1888(e)(2)(A)(iii)(II) through (V) of the Act, and as discussed in section IV.C. of the proposed rule.

The following is a summary of the public comment received on the proposed revisions to the regulation text and our response:

Comment: One commenter noted support for the regulation text revisions.

Response: We thank the commenter for their support. We did not receive any other comments on the proposed revisions to the regulation text, and therefore, we are finalizing the revisions as proposed.

VI. Other SNF PPS Issues

A. Rebasing and Revising the SNF Market Basket

Section 1888(e)(5)(A) of the Act requires the Secretary to establish a market basket index that reflects the changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary

services, and capital-related expenses. We use the SNF market basket index, adjusted in the manner described in section III.B. of this final rule, to update the SNF PPS per diem rates and to determine the labor-related share on an annual basis.

The SNF market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (the base period is 2018) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories and the proportion of total costs that each category represents is calculated. These proportions are called cost or expenditure weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

Effective for cost reporting periods beginning on or after July 1, 1998, we revised and rebased our 1977 routine costs input price index and adopted a total expenses SNF input price index using FY 1992 as the base year. In the FY 2002 SNF PPS final rule (66 FR 39582), we rebased and revised the market basket to a base year of FY 1997. In the FY 2008 SNF PPS final rule (72 FR 43425), we rebased and revised the market basket to a base year of FY 2004. In the FY 2014 SNF PPS final rule (78 FR 47939), we revised and rebased the SNF market basket, which included updating the base year from FY 2004 to FY 2010. Lastly, in the FY 2018 SNF PPS final rule (82 FR 36548), we revised and rebased the SNF market basket, which included updating the base year from FY 2010 to FY 2014. In the FY 2022 SNF PPS proposed rule (86 FR 19969 through 19984) we proposed to rebase and revise the market basket updating the base year from 2014 to 2018. Below is our methodology, as well as responses to comments.

Effective for FY 2022 and subsequent fiscal years, we will rebase and revise the market basket to reflect 2018 Medicare-allowable total cost data (routine, ancillary, and capital-related) from freestanding SNFs and to revise applicable cost categories and price proxies used to determine the market basket. Medicare-allowable costs are those costs that are eligible to be paid under the SNF PPS. For example, the SNF market basket excludes home health agency (HHA) costs as these costs would be paid under the HHA PPS, and therefore, these costs are not SNF PPS Medicare-allowable costs. We will maintain our policy of using data from freestanding SNFs, which represent about 93 percent of the total SNFs shown in Table 12. We believe using freestanding Medicare cost report (MCR) data, as opposed to the hospital-based SNF MCR data, for the cost weight calculation is most appropriate because of the complexity of hospital-based data and the representativeness of the freestanding data. Because hospital-based SNF expenses are embedded in the hospital cost report, any attempt to incorporate data from hospital-based facilities requires more complex calculations and assumptions regarding the ancillary costs related to the hospital-based SNF unit. We believe the use of freestanding SNF cost report data is technically appropriate for reflecting the cost structures of SNFs serving Medicare beneficiaries.

We will use 2018 as the base year as we believe that the 2018 MCRs represent the most recent, complete set of MCR data available to develop cost weights for SNFs at the time of rulemaking. We believe it is important to regularly rebase and revise the SNF market to reflect more recent data. Historically, the cost weights change minimally from year to year as they represent percent of total costs rather than cost levels; however, given the COVID–19 PHE, we will continue to monitor the upcoming MCR data to see if a more frequent rebasing schedule is necessary than our recent historical precedent of about every 4 years. The 2018 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2017 and before October 1, 2018. While these dates appear to reflect fiscal year data, we note that a Medicare cost report that begins in this timeframe is generally classified as a ''2018 cost report''. For example, we found that of the available 2018 Medicare cost reports for SNFs, approximately 7 percent had an October 1, 2017 begin date, approximately 70 percent of the reports had a January 1, 2018 begin date, and approximately 12 percent had a July 1, 2018 begin date. For this reason, we are defining the base year of the market basket as ''2018-based'' instead of ''FY 2018-based''.

Comment: Several commenters supported the rebasing and revising of the market basket, stating that a relevant market basket is a fundamental requirement for a well-functioning PPS. One commenter appreciated the proposed rebasing and revising of the SNF market basket as proposed and further stated that the use of the 2018 data is more reflective of current costs of providing services compared to 2014 data. Several commenters also supported CMS' plans to monitor and revise and rebase more frequently.

Response: We appreciate the commenters' support of the rebasing and revising of the SNF market basket and note that we plan to review the 2020 Medicare cost report data as soon as complete information is available to assess any impact of the PHE on the market basket relative cost shares. Any changes to the market basket would be proposed in rulemaking and will be subject to public comments.

We proposed to develop cost category weights for the 2018-based SNF market basket in two stages. First, we proposed to derive eight major expenditures or cost weights from the 2018 MCR data (CMS Form 2540–10, OMB NO. 0938–0463) for freestanding SNFs: Wages and Salaries; Employee Benefits; Contract Labor; Pharmaceuticals; Professional Liability Insurance; Home Office/Related Organization Contract Labor; Capital-related; and a residual ''All Other''. These are the same cost categories calculated using the 2014 MCR data for the 2014-based SNF market basket. The residual ''All Other'' category would reflect all remaining costs that are not captured in the other seven cost categories. Second, we proposed to divide the residual ''All Other'' cost category into more detailed subcategories, using U.S. Department of Commerce Bureau of Economic Analysis' (BEA) 2012 Benchmark Input-Output (I–O) ''use table before redefinitions, purchaser's value'' for the Nursing and Community Care Facilities industry (NAICS 623A00) aged to 2018 using applicable price proxy growth for each category of costs. Furthermore, we proposed to continue to use the same overall methodology as was used for the 2014-based SNF market basket to

develop the capital related cost weights of the 2018-based SNF market basket.

1. Development of Cost Categories and Weights

a. Use of Medicare Cost Report Data To Develop Major Cost Weights

In order to create a market basket that is representative of freestanding SNF providers serving Medicare patients and to help ensure accurate major cost weights (which is the percent of total Medicare-allowable costs, as defined below), we proposed to apply edits to remove reporting errors and outliers. Specifically, the SNF MCRs used to calculate the market basket cost weights exclude any providers that reported costs less than or equal to zero for the following categories: Total facility costs (Worksheet B, part 1, column 18, line 100); total operating costs (Worksheet B, part 1, column 18, line 100 less Worksheet B, part 2, column 18, line 100); Medicare general inpatient routine service costs (Worksheet D, part 1, column 1, line 1); and Medicare PPS payments (Worksheet E, part 3, column 1, line 1). We also limited our sample to providers that had a MCR reporting period that was between 10 and 14 months. The final sample used included roughly 13,500 MCRs (about 90 percent of the universe of SNF MCRs for 2018). The sample of providers is representative of the national universe of providers by region, by ownership-type (proprietary, nonprofit, and government), and by urban/rural status. Additionally, for all of the major cost weights, except Home Office/Related Organization Contract Labor costs, the data are trimmed to remove outliers (a standard statistical process) by: (1) Requiring that major expenses (such as Wages and Salaries costs) and total Medicare-allowable costs are greater than zero; and (2) excluding the top and bottom 5 percent of the major cost weight (for example, Wages and Salaries costs as a percent of total Medicare-allowable costs). We note that missing values are assumed to be zero, consistent with the methodology for how missing values are treated in the 2014-based market basket methodology.

For the Home Office/Related Organization Contract Labor cost weight, we proposed to first exclude providers whose Home Office/Related Organization Contract Labor costs are greater than Medicare-allowable total costs and then apply a trim that excludes those reporters with a Home Office/Related Organization Contract Labor cost weight above the 99th percentile. This allows providers with no Home Office/Related Organization Contract Labor costs to be included in the Home Office/Related Organization Contract Labor cost weight calculation . If we were to trim the top and bottom Home Office/Related Organization Contract Labor cost weight, we would exclude providers with a zero cost weight and the MCR data (Worksheet S–2 line 45) indicate that not all SNF providers have a home office. Providers without a home office would report administrative costs that might typically be associated with a home office in the Wages and Salaries and Employee Benefits cost weights, or in the residual ''All-Other'' cost weight if they purchased these types of services from external contractors. We believe the trimming methodology that excludes those who report Home Office costs above the 99th percentile is appropriate as it removes extreme outliers while also allowing providers with zero Home Office/Related Organization Contract Labor costs to be included in the Home Office/Related Organization Contract Labor cost weight calculation.

The trimming process is done individually for each cost category so that providers excluded from one cost weight calculation are not automatically excluded from another cost weight calculation. We note that these trimming methods are the same types of edits performed for the 2014-based SNF market basket, as well as other PPS market baskets (including but not limited to the IPPS market basket and HHA market basket). We believe this trimming process improves the accuracy of the data used to compute the major cost weights by removing possible data misreporting.

The final weights of the 2018-based SNF market basket are based on weighted means. For example, the aggregate Wages and Salaries cost weight, after trimming, is equal to the sum of total Medicare-allowable wages and salaries of all providers divided by the sum of total Medicare-allowable costs for all providers in the sample. This methodology is consistent with the methodology used to calculate the 2014-based SNF market basket cost weights and other PPS market basket cost weights. We note that for each of the cost weights, we evaluated the distribution of providers and costs by region, by ownership-type, and by urban/rural status. For all of the cost weights, with the exception of the PLI (which is discussed in more detail later), the trimmed sample was nationally representative.

For all of the cost weights, we use Medicare-allowable total costs as the denominator (for example, Wages and Salaries cost weight = Wages and Salaries costs divided by Medicare-allowable total costs). Medicare-allowable total costs were equal to total costs (after overhead allocation) from Worksheet B part I, column 18, for lines 30, 40 through 49, 51, 52, and 71 plus estimated Medicaid drug costs, as defined below. We included estimated Medicaid drug costs in the pharmacy cost weight, as well as the denominator for total Medicare-allowable costs. This is the same methodology used for the 2014-based SNF market basket. The inclusion of Medicaid drug costs was finalized in the FY 2008 SNF PPS final rule (72 FR 43425 through 43430), and for the same reasons set forth in that final rule, we proposed to continue to use this methodology in the 2018-based SNF market basket.

We describe the detailed methodology for obtaining costs for each of the eight cost categories determined from the Medicare Cost Report below. The methodology used in the 2014-based SNF market basket can be found in the FY 2018 SNF PPS final rule (82 FR 36548 through 36555).

(1) *Wages and Salaries:* To derive Wages and Salaries costs for the Medicare-allowable cost centers, we proposed first to calculate total facility wages and salaries costs as reported on Worksheet S–3, part II, column 3, line 1. We then proposed to remove the wages and salaries attributable to non-Medicare-allowable cost centers (that is, excluded areas), as well as a portion of overhead wages and salaries attributable to these excluded areas. Excluded area wages and salaries are equal to wages and salaries as reported on Worksheet S–3, part II, column 3, lines 3, 4, and 7 through 11 plus nursing facility and non-reimbursable salaries from Worksheet A, column 1, lines 31, 32, 50, and 60 through 63.

Overhead wages and salaries are attributable to the entire SNF facility; therefore, we proposed to include only the proportion attributable to the Medicare-allowable cost centers. We proposed to estimate the proportion of overhead wages and salaries attributable to the non-Medicare-allowable costs centers in two steps. First, we proposed to estimate the ratio of excluded area wages and salaries (as defined above) to non-overhead total facility wages and salaries (total facility wages and salaries (Worksheet S–3, part II, column 3, line 1) less total overhead wages and salaries (Worksheet S–3, Part III, column 3, line 14)). Next, we proposed to multiply total overhead wages and salaries by the ratio computed in step 1. We excluded providers whose excluded areas wages and salaries were greater than total facility wages and salaries and/or their

excluded area overhead wages and salaries were greater than total facility wages and salaries (about 50 providers). This is similar to the methodology used to derive Wages and Salaries costs in the 2014-based SNF market basket. For the 2014-based SNF market basket, we estimated the proportion of overhead wages and salaries that is attributable to the non-Medicare allowable costs centers (that is, excluded areas) by multiplying the ratio of excluded area wages and salaries (as defined above) to total wages and salaries as reported on Worksheet S–3, Part II, column 3, line 1 by total overhead wages and salaries as reported on Worksheet S–3, Part III, column 3, line 14.

(2) *Employee Benefits:* Medicare-allowable employee benefits are equal to total facility benefits as reported on Worksheet S–3, part II, column 3, lines 17 through 19 minus non-Medicare-allowable (that is, excluded area) employee benefits and minus a portion of overhead benefits attributable to these excluded areas. Excluded area employee benefits are derived by multiplying total excluded area wages and salaries (as defined above in the 'Wages and Salaries' section) times the ratio of total facility benefits to total facility wages and salaries. This ratio of benefits to wages and salaries is defined as total facility benefit costs to total facility wages and salary costs (as reported on Worksheet S–3, part II, column 3, line 1). Likewise, the portion of overhead benefits attributable to the excluded areas is derived by multiplying overhead wages and salaries attributable to the excluded areas (as defined in the 'Wages and Salaries' section) times the ratio of total facility benefit costs to total facility wages and salary costs (as defined above). Similar to the Wages and Salaries cost weight, we excluded providers whose excluded areas benefits were greater than total facility benefits and/or their excluded area overhead benefits were greater than total facility benefits (zero providers were excluded because of this edit). This is similar to the methodology used to derive Employee Benefits costs in the 2014-based SNF market basket.

(3) *Contract Labor:* We proposed to derive Medicare-allowable contract labor costs from Worksheet S–3, part II, column 3, line 14, which reflects costs for contracted direct patient care services (that is, nursing, therapeutic, rehabilitative, or diagnostic services furnished under contract rather than by employees and management contract services). This is the same methodology used to derive the Contract Labor costs in the 2014-based SNF market basket.

(4) *Pharmaceuticals:* We proposed to calculate pharmaceuticals costs using the non-salary costs from the Pharmacy cost center (Worksheet B, part I, column 0, line 11 less Worksheet A, column 1, line 11) and the Drugs Charged to Patients' cost center (Worksheet B, part I, column 0, line 49 less Worksheet A, column 1, line 49). Since these drug costs were attributable to the entire SNF and not limited to Medicare-allowable services, we proposed to adjust the drug costs by the ratio of Medicare-allowable pharmacy total costs (Worksheet B, part I, column 11, for lines 30, 40 through 49, 51, 52, and 71) to total pharmacy costs from Worksheet B, part I, column 11, line 11. Worksheet B, part I allocates the general service cost centers, which are often referred to as ''overhead costs'' (in which pharmacy costs are included) to the Medicare-allowable and non-Medicare-allowable cost centers. This adjustment was made for those providers who reported Pharmacy cost center expenses. Otherwise, we assumed the non-salary Drugs Charged to Patients costs were Medicare-allowable. Since drug costs for Medicare patients are included in the SNF PPS per diem rate, a provider with Medicare days should have also reported costs in the Drugs Charged to Patient cost center. We found a small number of providers (roughly 60) did not report Drugs Charged to Patients' costs despite reporting Medicare days (an average of about 2,600 Medicare days per provider), and therefore, these providers were excluded from the Pharmaceuticals cost weight calculations. This is similar to the methodology used for the 2014-based SNF market basket.

Second, as was done for the 2014-based SNF market basket, we proposed to continue to adjust the drug expenses reported on the MCR to include an estimate of total Medicaid drug costs, which are not represented in the Medicare-allowable drug cost weight. As stated previously in this section, the 2018-based SNF market basket reflects total Medicare-allowable costs (that is, total costs for all payers for those services reimbursable under the SNF PPS). For the FY 2006-based SNF market basket (72 FR 43426), commenters noted that the total pharmaceutical costs reported on the MCR did not include pharmaceutical costs for dual-eligible Medicaid patients as these were directly reimbursed by Medicaid. Since all of the other cost category weights reflect expenses associated with treating Medicaid patients (including the compensation costs for dispensing these drugs), we made an adjustment to include these Medicaid drug expenses so the market basket cost weights would be calculated consistently.

Similar to the 2014-based SNF market basket, we proposed to estimate Medicaid drug costs based on data representing dual-eligible Medicaid beneficiaries. Medicaid drug costs are estimated by multiplying Medicaid dual-eligible drug costs per day times the number of Medicaid days as reported in the Medicare-allowable skilled nursing cost center (Worksheet S–3, part I, column 5, line 1) in the SNF MCR. Medicaid dual-eligible drug costs per day (where the day represents an unduplicated drug supply day) were estimated using 2018 Part D claims for those dual-eligible beneficiaries who had a Medicare SNF stay during the year. The total drug costs per unduplicated day for 2018 of $24.48 represented all drug costs (including the drug ingredient cost, the dispensing fee, vaccine administration fee and sales tax) incurred during the 2018 calendar year for those dual-eligible beneficiaries who had a SNF Medicare stay during that 2018 calendar year. Therefore, they include drug costs incurred during a Medicaid SNF stay occurring in the 2018 calendar year. By comparison, the 2014-based SNF market basket also relied on data from the Part D claims, which yielded a dual-eligible Medicaid drug cost per day of $19.62 for 2014.

We continue to believe that Medicaid dual-eligible beneficiaries are a reasonable proxy for the estimated drug costs per day incurred by Medicaid patients staying in a skilled nursing unit under a Medicaid stay. The skilled nursing unit is the Medicare-allowable unit in a SNF, which encompasses more skilled nursing and rehabilitative care compared to a nursing facility or long-term care unit. We believe that Medicaid patients receiving this skilled nursing care would on average have similar drug costs per day to dual-eligible Medicare beneficiaries who have received Medicare skilled nursing care in the skilled nursing care unit during the year. We note that our previous analysis of the Part D claims data showed that Medicare beneficiaries with a SNF stay during the year have higher drug costs than Medicare patients without a SNF stay during the year. Also, in 2018, dual-eligible beneficiaries with a SNF stay during the year had drug costs per day of $24.48, which were approximately two times higher than the drug costs per day of $13.19 for nondual-eligible beneficiaries with a SNF Part A stay during the year.

The Pharmaceuticals cost weight using only 2018 MCR data (without the

inclusion of the Medicaid dual-eligible drug costs) is 2.6 percent, compared to the proposed Pharmaceuticals cost weight (including the adjustment for Medicaid dual-eligible drug costs) of 7.5 percent. The 2014-based SNF market basket had a Pharmaceuticals cost weight using only 2014 MCR data without the inclusion of the Medicaid dual-eligible drug costs of 2.9 percent and a total Pharmaceuticals cost weight of 7.3 percent. Therefore, the 0.2 percentage point increase in the Pharmaceuticals cost weight is a result of a 0.5-percentage point increase in the Medicaid dual-eligible drug cost weight (reflecting the 25 percent increase in the Medicaid dual-eligible drug costs per day between 2014 and 2018) and a 0.3-percentage point decrease in the MCR drug cost weight. The decrease in the MCR drug cost weight was consistent, in aggregate, across urban and rural status SNFs as well as across for-profit, government, and nonprofit ownership type SNFs.

(5) *Professional Liability Insurance:* We proposed to calculate the professional liability insurance (PLI) costs from Worksheet S–2 of the MCRs as the sum of premiums; paid losses; and self-insurance (Worksheet S–2, Part I, columns 1 through 3, line 41). This was the same methodology used to derive the Professional Liability costs for the 2014-based SNF market basket.

About 60 percent of SNFs (about 8,000) reported professional liability costs. After trimming, about 7,200 (reflecting about 850,000 Skilled Nursing unit beds) were included in the calculation of the PLI cost weight for the 2018-based SNF market basket. These providers treated roughly 870,000 Medicare beneficiaries and had a Medicare length of stay (LOS) of 33 days, a skilled nursing unit occupancy rate of 80 percent, and an average skilled nursing unit bed size of 125 beds, which are all consistent with the national averages. We also verified that this sample of providers are representative of the national distribution of providers by ownership-type and urban/rural status. We note that the sample of providers is less consistent with the national distribution of providers by region; however, we performed a sensitivity analysis where the PLI cost weight was reweighted based on the national regional distribution and the impacts were less than a 0.1 percentage point on the cost weight.

We note that based on prior comments during the rebasing of the 2014-based SNF market basket, we reviewed in detail the AON 2018 Professional and General Liability Benchmark for Long Term Care Providers [2] that examines professional liability and general liability claim costs for long term care providers (including skilled nursing facility beds as well as independent living, assisted living, home health care, and rehabilitation facilities, representing about 186,000 long term care beds). This study, although informative, was not appropriate for calculating a PLI cost weight as it represents more than just SNFs serving Medicare patients and captures claim losses as opposed to PLI costs (premiums, paid losses, and self-insurance) incurred during a cost reporting year. We note that only 13 percent of providers reported PLI paid losses or PLI self-insurance costs on the MCR while over 90 percent of providers reported PLI premiums indicating that the majority of losses incurred by Medicare participating SNFs will be covered by insurance premiums paid over time. Our comparison of the MCR data to the AON study for those select states' data provided did show consistencies between the average state PLI costs per bed relative to the national average (as measured by the MCR) and AON's loss per occupied bed relative to national values indicating that states with higher losses per occupied bed have higher PLI costs per total bed.

We believe the MCR data continues to be the most appropriate data source to calculate the PLI cost weight for the 2018-based SNF market basket as it is representative of SNFs serving Medicare beneficiaries and reflects PLI costs (premiums, paid losses, and self-insurance) incurred during the provider's cost reporting year.

(6) *Capital-Related:* We proposed to derive the Medicare-allowable capital-related costs from Worksheet B, part II, column 18 for lines 30, 40 through 49, 51, 52, and 71. This is the same methodology to derive capital-related costs used in the 2014-based SNF market basket.

(7) *Home Office/Related Organization Contract Labor Costs:* We proposed to calculate Medicare-allowable Home Office/Related Organization Contract Labor costs to be equal to data reported on Worksheet S–3, part II, column 3, line 16. We note that for the 2014-based SNF market basket we also used Worksheet S–3, part II, column 3, line 16 (Home office salaries & wage related costs) to determine these expenses; however, we referred to this category as Home Office Contract Labor Costs. The instructions for this data state ''enter the salaries and wage related costs (as defined on lines 17 and 18 below) paid to personnel who are affiliated with a home office and/or related organization, who provide services to the SNF and/or NF, and whose salaries are not included on Worksheet A, column 1,'' and therefore, we are referring to this cost category as Home Office/Related Organization Contract Labor costs. Furthermore, for this rebasing we no longer adjusted these expenses by the ratio of Medicare allowable operating costs to total facility operating costs as done for the 2014-based SNF market basket as the instructions indicate these expenses are for the SNF and NF units.

About 7,000 providers (about 53 percent) in 2018 reported having a home office (as reported on Worksheet S–2, part I, line 45); a lower share of providers than those in the 2014-based SNF market basket. As discussed in section VI.A.1. of this final rule, providers without a home office can incur these expenses directly by having their own staff, for which the costs would be included in the Wages and Salaries and Employee Benefits cost weights. Alternatively, providers without a home office could also purchase related services from external contractors for which these expenses would be captured in the residual ''All-Other'' cost weight. For this reason, unlike the other major cost weights described previously, we did not exclude providers that did not report Home Office/Related Organization Contract Labor costs. We note that this is similar to the methodology that was used for other PPS market baskets such as the 2017-based LTCH market basket (85 FR 58911).

(8) *All Other (residual):* The ''All Other'' cost weight is a residual, calculated by subtracting the major cost weights (Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, Capital-Related, and Home Office/Related Organization Contract Labor) from 100.

Table 12 shows the major cost categories and their respective cost weights as derived from the 2018 Medicare cost reports.

[2] *https://www.aon.com/risk-services/thought-leadership/report-2018-long-term-care.jsp.*

TABLE 12: Major Cost Categories Derived from the SNF Medicare Cost Reports*

Major Cost Categories	2018-based	2014-Based
Wages and Salaries	44.1	44.3
Employee Benefits	8.6	9.3
Contract Labor	7.5	6.8
Pharmaceuticals	7.5	7.3
Professional Liability Insurance	1.1	1.1
Capital-related	8.2	7.9
Home Office/Related Organization Contract Labor	0.7	0.7
All other (residual)	22.3	22.6

*Total may not sum to 100 due to rounding.

Compared to the 2014-based SNF market basket, the Wages and Salaries cost weight and the Employee Benefits cost weight as calculated directly from the Medicare cost reports decreased by 0.2 percentage point and 0.7 percentage point, respectively. The Contract Labor cost weight increased 0.7 percentage point and so in aggregate, the Compensation cost weight decreased 0.2 percentage point.

As we did for the 2014-based SNF market basket (82 FR 36555), we proposed to allocate contract labor costs to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. Using the 2018 Medicare cost report data, this percentage is 84 percent (1 percentage point higher than the percent in the 2014-based SNF market basket); therefore, we proposed to allocate approximately 84 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 16 percent to the Employee Benefits cost weight.

Table 13 shows the Wages and Salaries and Employee Benefits cost weights after contract labor allocation for the 2018-based SNF market basket and the 2014-based SNF market basket.

TABLE 13: Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation

Major Cost Categories	2018-based Market Basket	2014-Based Market Basket
Wages and Salaries	50.4	50.0
Employee Benefits	9.9	10.5

b. Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2018 Medicare cost report data into more detailed cost categories, we proposed to use the 2012 Benchmark I–O ''Use Tables/Before Redefinitions/Purchaser Value'' for Nursing and Community Care Facilities industry (NAICS 623A00), published by the Census Bureau's, Bureau of Economic Analysis (BEA). These data are publicly available at *http://www.bea.gov/industry/io_annual.htm.* The BEA Benchmark I–O data are generally scheduled for publication every 5 years with 2012 being the most recent year for which data is available. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts; therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[3] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates are less comprehensive and provide less detail than benchmark data. Additionally, the annual I–O data are subject to revision once benchmark data become available. For these reasons, we proposed to inflate the 2012 Benchmark I–O data aged forward to 2018 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. Next, the relative shares of the cost shares that each cost category represents to the total residual I–O costs are calculated. These resulting 2018 cost shares of the I–O data are applied to the ''All Other'' residual cost weight to obtain detailed cost weights for the residual costs for the 2018-based SNF market basket. For example, the cost for Food: Direct Purchases represents 11.3 percent of the sum of the ''All Other'' 2012 Benchmark I–O Expenditures inflated to 2018. Therefore, the Food: Direct Purchases cost weight is 2.5 percent of the 2018-based SNF market basket (11.3 percent × 22.3 percent = 2.5 percent). For the 2014-based SNF market basket (82 FR 36553), we used a similar methodology utilizing the 2007 Benchmark I–O data (aged to 2014).

Using this methodology, we proposed to derive 19 detailed SNF market basket cost category weights from the 2018-based SNF market basket ''All Other'' residual cost weight (22.3 percent). These categories are: (1) Fuel: Oil and Gas; (2) Electricity and Other Non-Fuel Utilities; (3) Food: Direct Purchases; (4) Food: Contract Services; (5) Chemicals; (6) Medical Instruments and Supplies; (7) Rubber and Plastics; (8) Paper and Printing Products; (9) Apparel; (10) Machinery and Equipment; (11) Miscellaneous Products; (12)

[3] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

Professional Fees: Labor-Related; (13) Administrative and Facilities Support Services; (14) Installation, Maintenance, and Repair Services; (15) All Other: Labor-Related Services; (16) Professional Fees: Nonlabor-Related; (17) Financial Services; (18) Telephone Services; and (19) All Other: Nonlabor-Related Services. The 2014-based SNF market basket had separate cost categories for Postage services and Water and Sewerage. Due to the small weights (less than 0.1 percentage point), we proposed that Postage costs be included in the All Other: Non-labor-Related Services and Water and Sewerage costs be included in the Electricity and Other Non-Fuel Utilities category. We note that the machinery and equipment expenses are for equipment that is paid for in a given year and not depreciated over the asset's useful life. Depreciation expenses for moveable equipment are accounted for in the capital component of the 2018-based SNF market basket (described in section IV.A.1.c. of this final rule).

c. Derivation of the Detailed Capital Cost Weights

Similar to the 2014-based SNF market basket, we further divided the Capital-related cost weight into: Depreciation, Interest, Lease and Other Capital-related cost weights.

We calculated the depreciation cost weight (that is, depreciation costs excluding leasing costs) using depreciation costs from Worksheet S–2, column 1, lines 20 and 21. Since the depreciation costs reflect the entire SNF facility (Medicare and non-Medicare-allowable units), we used total facility capital costs (Worksheet B, Part I, Column 18, line 100) as the denominator. This methodology assumes that the depreciation of an asset is the same regardless of whether the asset was used for Medicare or non-Medicare patients. This methodology yielded depreciation costs as a percent of capital costs of 25.3 percent for 2018. We then apply this percentage to the 2018-based SNF market basket Medicare-allowable Capital-related cost weight of 8.2 percent, yielding a Medicare-allowable depreciation cost weight (excluding leasing expenses, which is described in more detail below) of 2.1 percent. To further disaggregate the Medicare-allowable depreciation cost weight into fixed and moveable depreciation, we proposed to use the 2018 SNF MCR data for end-of-the-year capital asset balances as reported on Worksheet A–7. The 2018 SNF MCR data showed a fixed/moveable split of 86/14. The 2014-based SNF market basket, which utilized the same data from the 2014 MCRs, had a fixed/moveable split of 83/17.

We also derived the interest expense share of capital-related expenses from 2018 SNF MCR data, specifically from Worksheet A, column 2, line 81. Similar to the depreciation cost weight, we calculated the interest cost weight using total facility capital costs. This methodology yielded interest costs as a percent of capital costs of 22.8 percent for 2018. We then apply this percentage to the 2018-based SNF market basket Medicare-allowable Capital-related cost weight of 8.2 percent, yielding a Medicare-allowable interest cost weight (excluding leasing expenses) of 1.9 percent. As done with the last rebasing (82 FR 36556), we proposed to determine the split of interest expense between for-profit and not-for-profit facilities based on the distribution of long-term debt outstanding by type of SNF (for-profit or not-for-profit/government) from the 2018 SNF MCR data. We estimated the split between for-profit and not-for-profit interest expense to be 25/75 percent compared to the 2014-based SNF market basket with 27/73 percent.

Because the detailed data were not available in the MCRs, we used the most recent 2017 Census Bureau Service Annual Survey (SAS) data to derive the capital-related expenses attributable to leasing and other capital-related expenses. The 2014-based SNF market basket used the 2014 SAS data. We note that we proposed to use the 2017 SAS data because the Census Bureau no longer publishes these detailed capital-related expenses effective for 2018.

Based on the 2017 SAS data, we determined that leasing expenses are 62 percent of total leasing and capital-related expenses costs. In the 2014-based SNF market basket, leasing costs represent 63 percent of total leasing and capital-related expenses costs. We then apply this percentage to the 2018-based SNF market basket residual Medicare-allowable capital costs of 4.2 percent derived from subtracting the Medicare-allowable depreciation cost weight and Medicare-allowable interest cost weight from the 2018-based SNF market basket of total Medicare-allowable capital cost weight (8.2 percent − 2.1 percent − 1.9 percent = 4.2 percent). This produces the 2018-based SNF Medicare-allowable leasing cost weight of 2.6 percent and all-other capital-related cost weight of 1.6 percent.

Lease expenses are not broken out as a separate cost category in the SNF market basket, but are distributed among the cost categories of depreciation, interest, and other capital-related expenses, reflecting the assumption that the underlying cost structure and price movement of leasing expenses is similar to capital costs in general. As was done with past SNF market baskets and other PPS market baskets, we assumed 10 percent of lease expenses are overhead and assigned them to the other capital-related expenses cost category. This is based on the assumption that leasing expenses include not only depreciation, interest, and other capital-related costs but also additional costs paid to the lessor. We distributed the remaining lease expenses to the three cost categories based on the proportion of depreciation, interest, and other capital-related expenses to total capital costs, excluding lease expenses.

Table 14 shows the capital-related expense distribution (including expenses from leases) in the 2018-based SNF market basket and the 2014-based SNF market basket.

TABLE 14: Comparison of the Capital-related Expense Distribution of the 2018-based SNF Market Basket and the 2014-based SNF Market Basket

Cost Category	2018-based SNF Market Basket	2014-based SNF Market Basket
Capital-related Expenses	8.2	7.9
Total Depreciation	3.0	2.9
Total Interest	2.7	3.0
Other Capital-related Expenses	2.6	2.0

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal, and therefore, the detail capital cost weights may not add to the total capital-related expenses cost weight due to rounding.

Table 15 presents the 2018-based SNF market basket and the 2014-based SNF market basket.

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TABLE 15: 2018-based SNF Market Basket and 2014-based SNF Market Basket

Cost Category	2018-based SNF Market Basket	2014-based SNF Market Basket
Total	100.0	100.0
Compensation	60.2	60.4
Wages and Salaries1	50.4	50.0
Employee Benefits1	9.9	10.5
Utilities	1.5	2.6
Electricity and Other Non-Fuel Utilities	1.0	1.4
Fuel: Oil and Gas	0.4	1.3
Professional Liability Insurance	1.1	1.1
All Other	29.0	27.9
Other Products	17.6	14.3
Pharmaceuticals	7.5	7.3
Food: Direct Purchase	2.5	3.1
Food: Contract Purchase	4.3	0.7
Chemicals	0.2	0.2
Medical Instruments and Supplies	0.6	0.6
Rubber and Plastics	0.7	0.8
Paper and Printing Products	0.5	0.8
Apparel	0.5	0.3
Machinery and Equipment	0.5	0.3
Miscellaneous Products	0.3	0.3
All Other Services	11.5	13.6
Labor-Related Services	6.4	7.4
Professional Fees: Labor-related	3.5	3.8
Installation, Maintenance, and Repair Services	0.6	0.6
Administrative and Facilities Support	0.4	0.5
All Other: Labor-Related Services	1.9	2.5
Non Labor-Related Services	5.1	6.2
Professional Fees: Nonlabor-Related	2.0	1.8
Financial Services	1.3	2.0
Telephone Services	0.3	0.5
All Other: Nonlabor-Related Services3	1.5	2.0
Capital-Related Expenses	8.2	7.9
Total Depreciation	3.0	2.9
Building and Fixed Equipment	2.5	2.5
Movable Equipment	0.4	0.4
Total Interest	2.7	3.0
For-Profit SNFs	0.7	0.8
Government and Nonprofit SNFs	2.0	2.1
Other Capital-Related Expenses	2.6	2.0

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal, and therefore, the detailed cost weights may not add to the aggregate cost weights or to 100.0 due to rounding.
1. Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.
2. Water and Sewerage costs are included in the Electricity and Other Non-Fuel Utilities cost category in the 2018-based SNF market basket.
3. Postage costs are included in the All Other Non-labor-related cost category in the 2018-based SNF market basket.

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2. Price Proxies Used To Measure Operating Cost Category Growth

After developing the 27 cost weights for the 2018-based SNF market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of change for each expenditure category. With four

exceptions (three for the capital-related expenses cost categories and one for PLI), we base the wage and price proxies on Bureau of Labor Statistics (BLS) data, and group them into one of the following BLS categories:

• Employment Cost Indexes. Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the 2012 NAICS and the occupational ECIs are based on the 2000 and 2010 Standard Occupational Classification System (SOC).

• Producer Price Indexes. Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).

• Consumer Price Indexes. Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.) Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have proposed meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 20 lists all price proxies for the 2018-based SNF market basket. Below is a detailed explanation of the price proxies used for each operating cost category.

• Wages and Salaries: We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Nursing Care Facilities (NAICS 6231; BLS series code CIU2026231000000I) to measure price growth of this category. NAICS 623 includes facilities that provide a mix of health and social services, with many of the health services being largely some level of nursing services. Within NAICS 623 is NAICS 6231, which includes nursing care facilities primarily engaged in providing inpatient nursing and rehabilitative services. These facilities, which are most comparable to Medicare-certified SNFs, provide skilled nursing and continuous personal care services for an extended period of time, and therefore, have a permanent core staff of registered or licensed practical nurses. This is the same index used in the 2014-based SNF market basket.

• Employee Benefits: We proposed to use the ECI for Benefits for Nursing Care Facilities (NAICS 6231) to measure price growth of this category. The ECI for Benefits for Nursing Care Facilities is calculated using BLS's total compensation (BLS series ID CIU2016231000000I) for nursing care facilities series and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the Wages and Salaries price proxy section. This is the same index used in the 2014-based SNF market basket.

• Electricity and Other Non-Fuel Utilities: We proposed to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category as Electricity costs account for 93 percent of these expenses. This is the same index used for the Electricity cost category in the 2014-based SNF market basket. As previously noted, we proposed to include Water and Sewerage costs within the Electricity and Other Non-Fuel Utilities cost category, and to no longer use the CPI All Urban for Water and Sewerage Maintenance as we did for the 2014-based SNF market basket, due to the small size of this estimated cost weight (less than 0.1 percent).

Comment: One commenter noted that CMS is proposing to include water and sewerage costs in the Electricity and Other Non-Fuel utilities cost weight and to no longer use the CPI All Urban for Water and Sewerage Maintenance. They expressed concern stating that many SNFs have invested in waste-water monitoring systems as a result of COVID–19.

Response: We recognize the commenter's concern but as stated above, the most recent year of Benchmark I–O data we have available to derive the detailed cost weights for the SNF market basket is 2012, with the data generally scheduled for publication every 5 years. Based on these data, the cost weight associated with Water and Sewerage costs is less than 0.1 percent, and therefore, we do not believe a separate cost category is appropriate. We will continue to monitor new data for SNFs as it becomes available, including any new Benchmark I–O data, and will propose a rebasing or revising of the SNF market basket cost weights as appropriate.

• Fuel: Oil and Gas: We proposed to change the proxy used for the Fuel: Oil and Gas cost category. Our analysis of the Bureau of Economic Analysis' 2012 Benchmark I–O data for Nursing and Community Care Facilities shows approximately 96 percent of SNF Fuel: Oil and Gas expenses are for Petroleum Refineries (NAICS 324110), Natural gas (NAICS 221200), and Other Petroleum and Coal Products Manufacturing (NAICS 324190). We proposed to create a blended index based on those three NAICS chemical expenses listed above that account for 96 percent of SNF chemical expenses. We proposed to create this blend based on each NAICS' expenses as a share of their sum. Therefore, we proposed a blended proxy of 61 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411), 7 percent of the PPI

Commodity for Natural Gas (BLS series code WPU0531), and 32 percent of the PPI for Other Petroleum and Coal Products manufacturing (BLS series code PCU32419–32419).

The 2014-based SNF market basket also used a blended chemical proxy that was based on 2007 Benchmark I–O data. We believe our proposed Fuel: Oil and Gas blended index for the 2018-based SNF market basket is technically appropriate as it reflects more recent data on SNFs purchasing patterns. Table 16 provides the weights for the 2018-based blended chemical index and the 2014-based blended chemical index.

TABLE 16: Fuel: Oil and Gas Blended Index Weights

NAICS	Price Proxy	2018-based Index	2014-based Index
221200	PPI Commodity for Natural Gas	7%	35%
324110	PPI Industry for Petroleum Refineries	61%	65%
324190	PPI for Other Petroleum and Coal Products manufacturing	32%	n/a
	Total	100%	100%

• Professional Liability Insurance: We proposed to use the CMS Hospital Professional Liability Insurance Index to measure price growth of this category. We were unable to find a reliable data source that collects SNF-specific PLI data. Therefore, we proposed to use the CMS Hospital Professional Liability Index, which tracks price changes for commercial insurance premiums for a fixed level of coverage, holding non-price factors constant (such as a change in the level of coverage). This is the same index used in the 2014-based SNF market basket. We believe this is an appropriate proxy to measure the price growth associated of SNF PLI as it captures the price inflation associated with other medical institutions that serve Medicare patients.

• Pharmaceuticals: We proposed to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• Food: Wholesale Purchases: We proposed to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• Food: Retail Purchase: We proposed to use the CPI All Urban for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• Chemicals: For measuring price change in the Chemicals cost category, we proposed to use a blended PPI composed of the Industry PPIs for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519–32519), Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561–32561), and Other Miscellaneous Chemical Product Manufacturing (NAICS 325998) (BLS series code PCU325998325998).

Using the 2012 Benchmark I–O data, we found that these three NAICS industries accounted for approximately 96 percent of SNF chemical expenses. The remaining 4 percent of SNF chemical expenses are for three other incidental NAICS chemicals industries such as Paint and Coating Manufacturing. We proposed to create a blended index based on those three NAICS chemical expenses listed above that account for 96 percent of SNF chemical expenses. We proposed to create this blend based on each NAICS' expenses as a share of their sum. These expenses as a share of their sum are listed in Table 17.

The 2014-based SNF market basket also used a blended chemical proxy that was based on 2007 Benchmark I–O data. We believe our proposed chemical blended index for the 2018-based SNF market basket is technically appropriate as it reflects more recent data on SNFs purchasing patterns. Table 17 provides the weights for the 2018-based blended chemical index and the 2014-based blended chemical index.

TABLE 17: Chemical Blended Index Weights

NAICS	Price Proxy	2018-based Index	2014-based Index
325190	PPI for Other Basic Organic Chemical Manufacturing	34%	22%
325610	PPI for Soap and Cleaning Compound Manufacturing	21%	37%
325998	PPI for Other Miscellaneous Chemical Product Manufacturing	45%	41%
	Total	100%	100%

• Medical Instruments and Supplies: We proposed to change the proxy used for the Medical Instruments and Supplies cost weight. The 2012 Benchmark I–O data shows 46 percent of medical instruments and supply costs are for Surgical and medical instrument manufacturing costs (NAICS 339112) and 54 percent are for Surgical appliance and supplies manufacturing costs (NAICS 339113). To proxy the price changes associated with NAICS 339112, we proposed using the PPI—Commodity—Surgical and medical instruments (BLS series code WPU1562). This the same price proxy we used in the 2014-based SNF market basket. To proxy the price changes associated with NAICS 339113, we proposed to use 50 percent for the PPI—Commodity—Medical and surgical

appliances and supplies (BLS series code WPU1563) and 50 percent for the PPI Commodity data for Miscellaneous products-Personal safety equipment and clothing (BLS series code WPU1571). The latter price proxy would reflect personal protective equipment including but not limited to face shields and protective clothing. The 2012 Benchmark I–O data does not provide specific expenses for personal protective equipment (which would be reflected in the NAICS 339113 expenses); however, we recognize that this category reflects costs faced by SNFs. In absence of any specific cost data on personal protective equipment, we proposed to include the PPI Commodity data for Miscellaneous products-Personal safety equipment and clothing (BLS series code WPU1571) in the blended proxy for Medical Instruments and Supplies cost category with a weight of 27 percent (that is, 50 percent of the NAICS 339113 expenses as a percent of the sum of NAICS 339113 and NAICS 339112 expenses from the I–O).

The 2014-based SNF market basket used a blend composed of 60 percent of the PPI Commodity for Medical and Surgical Appliances and Supplies (BLS series code WPU1563) and 40 percent of the PPI Commodity for Surgical and Medical Instruments (BLS series code WPU1562). Table 18 provides the proposed Medical Instruments and Supplies cost weight blended price proxy.

TABLE 18: Medical Instruments and Supplies Blended Index Weights

NAICS	Price Proxy	2018-based Index	2014-based Index
339112	PPI - Commodity - Surgical and medical instruments (WUI1562)	46%	40%
339113	PPI - Commodity - Medical and surgical appliances and supplies (WPU1563)	27%	60%
	PPI Commodity data for Miscellaneous products-Personal safety equipment and clothing (WPU1571)	27%	n/a
Total		100%	100%

Comment: One commenter appreciated CMS' proposal to modify the Medical Instruments and Supplies proxy to reflect personal protective equipment.

Response: We appreciate the commenter's support and recognize the need to reflect the prices of medical instruments and supplies purchased by SNFs.

- Rubber and Plastics: We proposed to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This is the same index used in the 2014-based SNF market basket.
- Paper and Printing Products: We proposed to use the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.
- Apparel: We proposed to use the PPI Commodity for Apparel (BLS series code WPU0381) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.
- Machinery and Equipment: We proposed to use the PPI Commodity for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.
- Miscellaneous Products: For measuring price change in the Miscellaneous Products cost category, we proposed to use the PPI Commodity for Finished Goods less Food and Energy (BLS series code WPUFD4131). Both food and energy are already adequately represented in separate cost categories and should not also be reflected in this cost category. This is the same index used in the 2014-based SNF market basket.
- Professional Fees: Labor-Related: We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same index used in the 2014-based SNF market basket.
- Administrative and Facilities Support Services: We proposed to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same index used in the 2014-based SNF market basket.
- Installation, Maintenance and Repair Services: We proposed to use the ECI for Total Compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this new cost category. This is the same index used in the 2014-based SNF market basket.
- All Other: Labor-Related Services: We proposed to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.
- Professional Fees: NonLabor-Related: We proposed to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same index used in the 2014-based SNF market basket.
- Financial Services: We proposed to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.
- Telephone Services: We proposed to use the CPI All Urban for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.
- All Other: NonLabor-Related Services: We proposed to use the CPI All Urban for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket. As previously noted, we proposed to include Postage costs within the All Other: NonLabor-Related Services cost category, and to no

longer use the CPI All Urban for Postage as we did for the 2014-based SNF market basket, due to the small size of this estimated cost weight (less than 0.1 percent).

3. Price Proxies Used To Measure Capital Cost Category Growth

We proposed to apply the same capital price proxies as were used in the 2014-based SNF market basket, with the exception of the For-profit interest cost category, and below is a detailed explanation of the price proxies used for each capital cost category. We also proposed to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is the same method that was used for the 2014-based SNF market basket and is described below.

- Depreciation—Building and Fixed Equipment: We proposed to use the BEA Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type). This BEA index is intended to capture prices for construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. This is the same index used in the 2014-based SNF market basket.
- Depreciation—Movable Equipment: We proposed to use the PPI Commodity for Machinery and Equipment (BLS series code WPU11). This price index reflects price inflation associated with a variety of machinery and equipment that would be utilized by SNFs, including but not limited to medical equipment, communication equipment, and computers. This is the same index used in the 2014-based SNF market basket.
- Nonprofit Interest: We proposed to use the average yield on Municipal Bonds (Bond Buyer 20-bond index). This is the same index used in the 2014-based SNF market basket.
- For-Profit Interest: For the For-Profit Interest cost category, we proposed to use the iBoxx AAA Corporate Bond Yield index instead of the Moody's AAA Corporate Bond Yield index that was used for the 2014-based SNF market basket. Effective for December 2020, the Moody's AAA Corporate Bond series is no longer available for use under license to IGI, the nationally-recognized economic and financial forecasting firm with whom we contract to forecast the components of the market baskets and MFP. Therefore, we proposed to replace the price proxy for the For-Profit interest cost category. We compared the iBoxx AAA Corporate Bond Yield index with the Moody's AAA Corporate Bond Yield index and found that the average growth rates in the two series were similar. Over the historical time period of FY 2000 to FY 2020, the 4-quarter percent change moving average growth in the iBoxx series was approximately 0.1 percentage point higher, on average, than the Moody's AAA corporate Bond Yield index.
- Other Capital: Since this category includes fees for insurances, taxes, and other capital-related costs, we proposed to use the CPI for Rent of Primary Residence (BLS series code CUUS0000SEHA), which would reflect the price growth of these costs. This is the same index used in the 2014-based SNF market basket.

We believe that these price proxies are the most appropriate proxies for SNF capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

As stated above, we proposed to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. To capture the long-term nature, the price proxies are vintage-weighted; and the vintage weights are calculated using a two-step process. First, we determine the expected useful life of capital and debt instruments held by SNFs. Second, we identify the proportion of expenditures within a cost category that is attributable to each individual year over the useful life of the relevant capital assets, or the vintage weights.

We rely on Bureau of Economic Analysis (BEA) fixed asset data to derive the useful lives of both fixed and movable capital, which is the same data source used to derive the useful lives for the 2014-based SNF market basket. The specifics of the data sources used are explained below.

a. Calculating Useful Lives for Moveable and Fixed Assets

Estimates of useful lives for movable and fixed assets for the 2018-based SNF market basket are 9 and 26 years, respectively. These estimates are based on three data sources from the BEA: (1) Current-cost average age; (2) historical-cost average age; and (3) industry-specific current cost net stocks of assets.

BEA current-cost and historical-cost average age data by asset type are not available by industry but are published at the aggregate level for all industries. The BEA does publish current-cost net capital stocks at the detailed asset level for specific industries. There are 64 detailed movable assets (including intellectual property) and there are 32 detailed fixed assets in the BEA estimates. Since we seek aggregate useful life estimates applicable to SNFs, we developed a methodology to approximate movable and fixed asset ages for nursing and residential care services (NAICS 623) using the published BEA data. For the 2018 SNF market basket, we use the current-cost average age for each asset type from the BEA fixed assets Table 2.9 for all assets and weight them using current-cost net stock levels for each of these asset types in the nursing and residential care services industry, NAICS 6230. (For example, nonelectro medical equipment current-cost net stock (accounting for about 35 percent of total moveable equipment current-cost net stock in 2018) is multiplied by an average age of 4.7 years. Current-cost net stock levels are available for download from the BEA website at *https://apps.bea.gov/iTable/index_FA.cfm.* We then aggregate the ''weighted'' current-cost net stock levels (average age multiplied by current-cost net stock) into moveable and fixed assets for NAICS 6230. We then adjust the average ages for moveable and fixed assets by the ratio of historical-cost average age (Table 2.10) to current-cost average age (Table 2.9).

This produces historical cost average age data for movable (equipment and intellectual property) and fixed (structures) assets specific to NAICS 6230 of 4.7 and 13.1 years for 2018, respectively. The average age reflects the average age of an asset at a given point in time, whereas we want to estimate a useful life of the asset, which would reflect the average over all periods an asset is used. To do this, we multiply each of the average age estimates by two to convert to average useful lives with the assumption that the average age is normally distributed (about half of the assets are below the average at a given point in time, and half above the average at a given point in time). This produces estimates of likely useful lives of 9.49 and 26.19 years for movable and fixed assets, which we round to 9 and 26 years, respectively. We proposed an interest vintage weight time span of 24 years, obtained by weighting the fixed and movable vintage weights (26 years and 9 years, respectively) by the fixed and movable split (86 percent and 14 percent, respectively). This is the same methodology used for the 2014-based SNF market basket, which had useful lives of 23 years and 10 years for fixed and moveable assets, respectively. We estimate that the impact of revising the

useful lives had a minor impact on the average historical growth rate of the 2018-based SNF market basket total aggregate capital cost price proxy. Over the FY 2016 to FY 2020 time period, the percent change moving average in the total aggregate capital cost price proxy was about 0.06 percentage point higher, on average, based on the 2018-based SNF market basket compared to the 2014-based SNF market basket.

b. Constructing Vintage Weights

Given the expected useful life of capital (fixed and moveable assets) and debt instruments, we must determine the proportion of capital expenditures attributable to each year of the expected useful life for each of the three asset types: Building and fixed equipment, moveable equipment, and interest. These proportions represent the vintage weights. We were not able to find a historical time series of capital expenditures by SNFs. Therefore, we approximated the capital expenditure patterns of SNFs over time, using alternative SNF data sources. For building and fixed equipment, we used the stock of beds in nursing homes from the National Nursing Home Survey (NNHS) conducted by the National Center for Health Statistics (NCHS) for 1962 through 1999. For 2000 through 2010, we extrapolated the 1999 bed data forward using a 5-year moving average of growth in the number of beds from the SNF MCR data. For 2011 to 2014, we extrapolate the 2010 bed data forward using the average growth in the number of beds over the 2011 to 2014 time period. For 2015 to 2018, we proposed to extrapolate the 2014 bed data forward using the average growth in the number of beds over the 2015 to 2018 time period. We then used the change in the stock of beds each year to approximate building and fixed equipment purchases for that year. This procedure assumes that bed growth reflects the growth in capital-related costs in SNFs for building and fixed equipment. We believe that this assumption is reasonable because the number of beds reflects the size of a SNF, and as a SNF adds beds, it also likely adds fixed capital.

As was done for the 2014-based SNF market basket (as well as prior market baskets), we proposed to estimate moveable equipment purchases based on the ratio of ancillary costs to routine costs. The time series of the ratio of ancillary costs to routine costs for SNFs measures changes in intensity in SNF services, which are assumed to be associated with movable equipment purchase patterns. The assumption here is that as ancillary costs increase compared to routine costs, the SNF caseload becomes more complex and would require more movable equipment. The lack of movable equipment purchase data for SNFs over time required us to use alternative SNF data sources. A more detailed discussion of this methodology was published in the FY 2008 SNF final rule (72 FR 43428). We believe the resulting two time series, determined from beds and the ratio of ancillary to routine costs, reflect real capital purchases of building and fixed equipment and movable equipment over time.

To obtain nominal purchases, which are used to determine the vintage weights for interest, we converted the two real capital purchase series from 1963 through 2018 determined above to nominal capital purchase series using their respective price proxies (the BEA Chained Price Index for Nonresidential Construction for Hospitals & Special Care Facilities and the PPI for Machinery and Equipment). We then combined the two nominal series into one nominal capital purchase series for 1963 through 2018. Nominal capital purchases are needed for interest vintage weights to capture the value of debt instruments.

Once we created these capital purchase time series for 1963 through 2018, we averaged different periods to obtain an average capital purchase pattern over time: (1) For building and fixed equipment, we averaged 31, 26-year periods; (2) for movable equipment, we averaged 48, 9-year periods; and (3) for interest, we averaged 33, 24-year periods. We calculate the vintage weight for a given year by dividing the capital purchase amount in any given year by the total amount of purchases during the expected useful life of the equipment or debt instrument. To provide greater transparency, we posted on the CMS market basket website at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html,* an illustrative spreadsheet that contains an example of how the vintage-weighted price indexes are calculated.

The vintage weights for the 2018-based SNF market basket and the 2014-based SNF market basket are presented in Table 19.

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TABLE 19: 2018-Based Vintage Weights and 2014-Based Vintage Weights

Year1	Building and Fixed Equipment		Movable Equipment		Interest	
	2018-based 26 years	2014-Based 23 years	2018-based 9 years	2014-Based 10 years	2018-based 24 years	2014-Based 21 years
1	0.049	0.056	0.135	0.085	0.027	0.032
2	0.050	0.055	0.140	0.087	0.028	0.033
3	0.049	0.054	0.128	0.091	0.029	0.034
4	0.047	0.052	0.112	0.097	0.031	0.036
5	0.045	0.049	0.119	0.099	0.032	0.037
6	0.043	0.046	0.111	0.102	0.034	0.039
7	0.041	0.044	0.084	0.108	0.036	0.041
8	0.040	0.043	0.080	0.109	0.037	0.043
9	0.037	0.040	0.091	0.110	0.038	0.044
10	0.035	0.038		0.112	0.040	0.045
11	0.036	0.038			0.043	0.048
12	0.036	0.039			0.047	0.052
13	0.036	0.039			0.049	0.056
14	0.036	0.039			0.051	0.058
15	0.035	0.039			0.050	0.060
16	0.036	0.039			0.048	0.059
17	0.036	0.040			0.048	0.057
18	0.038	0.041			0.048	0.057
19	0.037	0.043			0.048	0.056
20	0.036	0.042			0.048	0.056
21	0.035	0.042			0.047	0.057
22	0.035	0.042			0.047	
23	0.035	0.042			0.047	
24	0.033				0.049	
25	0.032					
26	0.032					
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: The vintage weights are calculated using thirteen decimals. For presentation purposes, we are displaying three decimals and therefore, the detail vintage weights may not add to 1.000 due to rounding.

1 Year 1 represents the vintage weight applied to the farthest year while the vintage weight for year 26, for example, would apply to the most recent year.

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Comment: Many commenters stated that COVID–19 has required SNFs to make significant changes in operations resulting in much higher operating costs as a result of increased labor, PPE, janitorial, and capital costs. They stated the new cost levels were permanent and noted that the 2018 data used to rebase the market basket would not reflect these cost levels. They recommended CMS account for these increased costs in the market basket.

Several commenters requested that CMS explore the temporary use of more heavily-weighted market basket elements to account for COVID–19 influenced cost increases, especially for both in-house and contract labor costs and capital costs. To account for the change in labor costs, some commenters recommended that CMS make an adjustment to the labor–related price proxy to account for the increase in wages and salaries and contract labor costs. One commenter recommended that CMS use the Payroll-Based Journal (PBJ) data and examine the wage rate differential between Agency and Employed Nurses/Aides using the labor data reported on Schedule S–3 Part V of the SNF Medicare cost reports. The commenter recommended that the greater proportion of Agency staff in the PBJ data when combined with the price differential between Employed vs Agency staff would result in an increase in the price proxy for labor (with labor being roughly 70 percent of costs).

One commenter listed testing of staff as one of the largest unbudgeted and unreimbursed costs for nursing homes. They stated that staff testing costs vary widely based on the size of the facility, types of tests used, and laboratory charges and on average have cost about 100 per week per staff member tested. Some commenters stated that some PPE allotments were provided by state and local governments; however, the amounts were inconsequential in comparison with the needs. Some commenters further requested that CMS consider additional under-detected costs due to room-sharing by more than one COVID–19 positive patient which was required by space constraints and/or isolation room shortages.

One commenter also recommended CMS inflate the capital costs noting that SNFs have incurred increased costs to reduce the spread of COVID–19 by investing in fresh air intake systems, air purification systems, and new heating ventilation and air conditions systems. They also cited additional costs

incurred in 2020 to invest in improved wireless technology and ultraviolet light. One commenter suggested that the capital costs should also reflect the increased costs of replacing and/or updating older facilities and the construction of larger facilities which would better position nursing facilities for any future pandemic situations.

Response: We appreciate the commenter's concern regarding the impact of COVID–19 on SNF costs. We reiterate that the SNF market basket is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not reflected. Changes in costs are taken into consideration and reflected when the market basket is rebased and the cost weights are revised to reflect the most recent cost structure. CMS proposed to rebase and revise the SNF market basket for FY 2022 since it has been 4 years since the last rebasing. The SNF market basket cost weights rely on the data reported on the Medicare cost reports, which provide the most comprehensive expense data available for the universe of SNFs. We proposed to use the data reported for 2018 because it is the most recent year of complete data available at the time of performing the analysis for the proposed SNF rule.

We understand that the COVID–19 pandemic has resulted in unanticipated challenges to SNF providers and all other healthcare provider settings. We note that the market basket updates account for the expected changes in the input prices, including labor, medical supplies, other products (including PPE), and capital. The price proxies take into account the changes in the expected prices of these good and services. The rates are set prospectively which requires forecasting the expected inflation pressures. The FY 2022 SNF payment update is based on the most recent forecast of expected price pressures that SNF providers will face in FY 2022. Additionally, the SNF payment update formula includes a forecast error adjustment if the difference between the historical SNF market basket growth and projected SNF market basket growth exceeds the forecast error threshold (in absolute terms). As discussed in section IV.B.3 of this final rule, the forecast error for FY 2020 is −0.8 percentage point indicating the SNF market basket update factor was higher than the actual SNF market basket growth. The same analysis will be considered for FY 2021 once historical data is available.

We also note that while the overall operating expenses may have been impacted for providers in 2020, the market basket cost share weights are based on the relative shares of expenses by category. CMS would need to have a dataset that would provide expenditure levels for all categories of expenses to determine the relative shares of each cost category and there is not a comprehensive set of 2020 cost data for SNF providers available at this time. It would be inappropriate to only make adjustments to select costs as suggested by the commenters. As stated previously, we plan to review the 2020 Medicare cost report data as soon as complete information is available to ensure the market basket relative cost shares are still appropriate.

Finally, we respectfully disagree that the capital cost weight in the market basket should reflect future costs of replacing and/or updating older facilities and the construction of larger facilities in order to better position nursing facilities for any future pandemic situations. The market basket cost weights are based on actual expenses that SNF facilities incur and reported on the Medicare cost reports.

After consideration of public comments, we are finalizing the 2018-based SNF market basket as proposed. Table 20 shows all the price proxies for the finalized 2018-based SNF market basket.

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TABLE 20: Price Proxies for the 2018-based SNF Market Basket

Cost Category	Weight	Price proxy
Total	100.0	
Compensation	60.2	
Wages and Salaries [1]	50.4	ECI for Wages and Salaries for Private Industry Workers in Nursing Care Facilities
Employee Benefits[1]	9.9	ECI for Total Benefits for Private Industry Workers in Nursing Care Facilities
Utilities	1.5	
Electricity and Other Non-Fuel Utilities	1.0	PPI Commodity for Commercial Electric Power
Fuel: Oil and Gas	0.4	Blend of Fuel PPIs
Professional Liability Insurance	1.1	CMS Professional Liability Insurance Premium Index
All Other	29.0	
Other Products	17.6	
Pharmaceuticals	7.5	PPI Commodity for Pharmaceuticals for Human Use, Prescription
Food: Direct Purchase	2.5	PPI Commodity for Processed Foods and Feeds
Food: Contract Purchase	4.3	CPI for Food Away From Home (All Urban Consumers)
Chemicals	0.2	Blend of Chemical PPIs
Medical Instruments and Supplies	0.6	Blend of Medical Instruments and Supplies PPIs
Rubber and Plastics	0.7	PPI Commodity for Rubber and Plastic Products
Paper and Printing Products	0.5	PPI Commodity for Converted Paper and Paperboard Products
Apparel	0.5	PPI Commodity for Apparel

Cost Category	Weight	Price proxy
Machinery and Equipment	0.5	PPI Commodity for Machinery and Equipment
Miscellaneous Products	0.3	PPI Commodity for Finished Goods Less Food and Energy
All Other Services	11.5	
Labor-Related Services	6.4	
Professional Fees: Labor-related	3.5	ECI for Total Compensation for Private Industry Workers in Professional and Related
Installation, Maintenance, and Repair Services	0.6	ECI for Total Compensation for All Civilian workers in Installation, Maintenance, and Repair
Administrative and Facilities Support	0.4	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
All Other: Labor-Related Services	1.9	ECI for Total Compensation for Private Industry Workers in Service Occupations
Non Labor-Related Services	5.1	
Professional Fees: Nonlabor-Related	2.0	ECI for Total Compensation for Private Industry Workers in Professional and Related
Financial Services	1.3	ECI for Total Compensation for Private Industry Workers in Financial Activities
Telephone Services	0.3	CPI for Telephone Services
All Other: Nonlabor-Related Services	1.5	CPI for All Items Less Food and Energy
Capital-Related Expenses	8.2	
Total Depreciation	3.0	
Building and Fixed Equipment	2.5	BEA's Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care - vintage weighted 26 years
Movable Equipment	0.4	PPI Commodity for Machinery and Equipment - vintage weighted 9 years
Total Interest	2.7	
For-Profit SNFs	0.7	iBoxx - Average yield on Aaa bond - vintage weighted 24 years
Government and Nonprofit SNFs	2.0	Bond Buyer - Average yield on Domestic Municipal Bonds - vintage weighted 24 years
Other Capital-Related Expenses	2.6	CPI for Rent of Primary Residence

Note: The cost weights are calculated using three decimal places. For presentation purposes, we are displaying one decimal, and therefore, the detailed cost weights may not add to the aggregate cost weights or to 100.0 due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

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4. Labor-Related Share

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. Each year, we calculate a revised labor-related share based on the relative importance of labor-related cost categories in the input price index. Effective for FY 2022, we proposed to revise and update the labor-related share to reflect the relative importance of the 2018-based SNF market basket cost categories that we believe are labor-intensive and vary with, or are influenced by, the local labor market. For the 2018-based SNF market basket these are: (1) Wages and Salaries (including allocated contract labor costs as described above); (2) Employee Benefits (including allocated contract labor costs as described above); (3) Professional fees: Labor-related; (4) Administrative and Facilities Support Services; (5) Installation, Maintenance, and Repair Services; (6) All Other: Labor-Related Services; and (7) a proportion of capital-related expenses. We proposed to continue to include a proportion of capital-related expenses because a portion of these expenses are deemed to be labor-intensive and vary with, or are influenced by, the local labor market. For example, a proportion of construction costs for a medical building would be attributable to local construction workers' compensation expenses.

Consistent with previous SNF market basket revisions and rebasings, the All Other: Labor-related services cost category is mostly comprised of building maintenance and security services (including, but not limited to, landscaping services, janitorial services, waste management services services) and dry cleaning and laundry services. Because these services tend to be labor-intensive and are mostly performed at the SNF facility or in the local area (and therefore, unlikely to be purchased in the national market), we believe that they meet our definition of labor-related services.

These are the same cost categories we have included in the LRS for the 2014-based SNF market basket rebasing (82 FR 36563), as well as the same categories included in the LRS for the 2016-based IRF market basket (84 FR 39087), 2016-based IPF market basket

(84 FR 38445), and 2017-based LTCH market basket (85 FR 58910).

As discussed in the FY 2018 SNF PPS proposed rule (82 FR 21040), in an effort to determine more accurately the share of nonmedical professional fees (included in the 2018-based SNF market basket Professional Fees cost categories) that should be included in the labor-related share, we surveyed SNFs regarding the proportion of those fees that are attributable to local firms and the proportion that are purchased from national firms. Based on these weighted results, we determined that SNFs purchase, on average, the following portions of contracted professional services inside their local labor market:

- 78 percent of legal services.
- 86 percent of accounting and auditing services.
- 89 percent of architectural, engineering services.
- 87 percent of management consulting services.

Together, these four categories represent 3.5 percentage points of the total costs for the 2018-based SNF market basket. We applied the percentages from this special survey to their respective SNF market basket weights to separate them into labor-related and nonlabor-related costs. As a result, we are designating 2.9 of the 3.5 percentage points total to the labor-related share, with the remaining 0.6 percentage point categorized as nonlabor-related.

In addition to the professional services as previously listed, for the 2018-based SNF market basket, we proposed to allocate a proportion of the Home Office/Related Organization Contract Labor cost weight, calculated using the Medicare cost reports as previously stated, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We proposed to classify these expenses as labor-related and nonlabor-related as many facilities are not located in the same geographic area as their home office, and therefore, do not meet our definition for the labor-related share that requires the services to be purchased in the local labor market.

Similar to the 2014-based SNF market basket, we proposed for the 2018-based SNF market basket to use the Medicare cost reports for SNFs to determine the home office labor-related percentages. The Medicare cost report requires a SNF to report information regarding its home office provider. Using information on the Medicare cost report, we compared the location of the SNF with the location of the SNF's home office. We proposed to classify a SNF with a home office located in their respective labor market if the SNF and its home office are located in the same Metropolitan Statistical Area (MSA). Then we determine the proportion of the Home Office/Related Organization Contract Labor cost weight that should be allocated to the labor-related share based on the percent of total Home Office/Related Organization Contract Labor costs for those SNFs that had home offices located in their respective local labor markets of total Home Office/Related Organization Contract Labor costs for SNFs with a home office. We determined a SNF's and its home office's MSA using their zip code information from the Medicare cost report. Using this methodology, we determined that 21 percent of SNFs' Home Office/Related Organization Contract Labor costs were for home offices located in their respective local labor markets. Therefore, we proposed to allocate 21 percent of the Home Office/Related Organization Contract Labor cost weight (0.14 percentage point = 0.69 percent × 21 percent) to the Professional Fees: Labor-related cost weight and 79 percent of the Home Office/Related Organization Contract Labor cost weight to the Professional Fees: Nonlabor-related cost weight (0.55 percentage point = 0.69 percent × 79 percent). The 2014-based SNF market basket used a similar methodology for allocating the Home Office/Related Organization Contract Labor cost weight to the labor-related share.

In summary, based on the two allocations mentioned earlier, we proposed to apportion 3.0 percentage points of the Professional Fees (2.9 percentage points) and Home Office/Related Organization Contract Labor (0.1 percentage point) cost weights into the Professional Fees: Labor-Related cost category. This amount was added to the portion of professional fees that we already identified as labor-related using the I–O data such as contracted advertising and marketing costs (approximately 0.45 percentage point of total costs) resulting in a Professional Fees: Labor-Related cost weight of 3.5 percent.

Based on IHS Global Inc. 2020q4 forecast with historical data thrugh 2020q3, we proposed a FY 2022 labor-related share of 70.1 percent (86 FR 19965).

Comment: A few commenters appreciated the reduction of the labor-related share from 71.3 percent to 70.1 percent for FY 2022.

Response: We appreciate the commenters' support. We believe that updating the labor-related share to reflect the more recent data of the 2018-based SNF market basket is appropriate to ensuring accurate payments to SNF providers.

Comment: One commenter urged CMS to reverse the decrease in the labor-related share from 71.3 percent to 70.1 percent in FY 2022. The commenter stated that a lower labor share does not reflect the experiences of SNFs during the PHE. They stated that SNFs face difficulty hiring and maintaining staff and to keep pace with labor shortages and also claim that average salary costs have increased over 2020.

Response: We disagree with the commenter's request to not finalize our proposal to determine the labor-related share for FY 2022 based on the proposed 2018-based SNF market basket. We believe that updating the labor share to reflect more recent cost data of the 2018-based SNF market basket is a technical improvement in determining the labor-related share. We also note that the SNF labor-related share is based on the relative importance of the labor-related categories and therefore, accounts for both a change to the base year weights (accounting for total spending) but also accounts for price changes from the base year to the FY 2022 payment period. Therefore, we believe that the LRS based on the 2018-based market basket is a technical improvement. As stated in the FY 2022 SNF PPS proposed rule (86 FR 19959), if more recent data became available (for example, a more recent estimate of the SNF market basket and/or productivity), we would use such data, if appropriate, to determine the FY 2022 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, or productivity adjustment in the FY 2022 SNF PPS final rule. Based on IGI's 2021q2 forecast (with historical data through 2021q1), the labor-related share of the finalized 2018-based SNF market basket is 70.4 percent.

Table 21 compares the FY 2022 labor-related share based on the 2018-based SNF market basket relative importance and the FY 2021 labor-related share based on the 2014-based SNF market basket relative importance as finalized in the FY 2021 SNF final rule (85 FR 47605).

TABLE 21: FY 2021 and FY 2022 SNF Labor-Related Share

	Relative importance, labor-related share, FY 2021 20:2 forecast [1]	Relative importance, labor-related share, FY 2022 21:2 forecast [2]
Wages and salaries [3]	51.1	51.4
Employee benefits*	9.9	9.5
Professional fees: Labor-related	3.7	3.5
Administrative & facilities support services	0.5	0.6
Installation, maintenance & repair services	0.6	0.4
All other: Labor-related services	2.6	2.0
Capital-related (0.391)	2.9	3.0
Total	71.3	70.4

[1] Published in the Federal Register (85 FR 47605); based on the second quarter 2020 IHS Global Inc. forecast of the 2014-based SNF market basket, with historical data through first quarter 2020.
[2] Based on the second quarter 2021 IHS Global Inc. forecast of the 2018-based SNF market basket, with historical data through first quarter 2021.
[3] The Wages and Salaries and Employee Benefits cost weight reflect contract labor costs as described above.

The FY 2022 SNF labor-related share is 0.9 percentage point lower than the FY 2021 SNF labor-related share (based on the 2014-based SNF market basket). The major reason for the lower labor-related share is due to the incorporation of the 2012 Benchmark I–O data, primarily stemming from a decrease in the All Other: Labor-related services and Professional Fees: Labor-related services cost weights, and a decrease in the Compensation cost weight as a result of incorporating the 2018 MCR data.

5. Market Basket Estimate for the FY 2022 SNF PPS Update

As discussed previously, beginning with the FY 2022 SNF PPS update, we are adopting the 2018-based SNF market basket as the appropriate market basket of goods and services for the SNF PPS. Consistent with historical practice, we estimate the market basket update for the SNF PPS based on IHS Global Inc.'s (IGI) forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets and multifactor productivity (MFP). Based on IGI's second quarter 2021 forecast with historical data through the first quarter of 2021, the most recent estimate of the 2018-based SNF market basket update for FY 2022 is 2.7 percent—which is the same update as the FY 2022 percent change of the 2014-based SNF market basket.

Table 22 compares the 2018-based SNF market basket and the 2014-based SNF market basket percent changes. For the historical period between FY 2017 and FY 2020, there is no difference in the average growth rates between the two market baskets. For the forecasted period between FY 2021 and FY 2023, the average difference in the growth rates between the two market baskets is −0.1 percentage point.

TABLE 22: 2018-based SNF Market Basket and 2014-based SNF Market Basket, Percent Changes: 2017-2023

Fiscal Year (FY)	2018-based SNF Market Basket	2014-based SNF Market Basket
Historical data:		
FY 2017	2.5	2.7
FY 2018	2.6	2.6
FY 2019	2.4	2.3
FY 2020	2.1	2.0
Average FY 2017-2020	2.4	2.4
Forecast:		
FY 2021	3.1	3.2
FY 2022	2.7	2.7
FY 2023	2.7	2.7
Average FY 2021-2023	2.8	2.9

Source: IHS Global, Inc. 2nd quarter 2021 forecast with historical data through 1st quarter 2021.

B. Technical Updates to PDPM ICD–10 Mappings

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of the Patient Driven Payment Model (PDPM), effective October 1, 2019. The PDPM utilizes International Classification of Diseases, Version 10 (ICD–10) codes in several ways, including to assign patients to clinical categories used for categorization under several PDPM components, specifically the PT, OT, SLP and NTA components. The ICD–10 code mappings and lists used under PDPM are available on the PDPM website at *https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/SNFPPS/PDPM.*

Each year, the ICD–10 Coordination and Maintenance Committee, a Federal interdepartmental committee that is chaired by representatives from the National Center for Health Statistics (NCHS) and by representatives from CMS, meets biannually and publishes updates to the ICD–10 medical code data sets in June of each year. These changes become effective October 1 of the year in which these updates are issued by the committee. The ICD–10 Coordination and Maintenance Committee also has the ability to make changes to the ICD–10 medical code data sets effective on April 1.

In the FY 2020 SNF PPS final rule (84 FR 38750), we outlined the process by which we maintain and update the ICD–10 code mappings and lists associated with the PDPM, as well as the SNF GROUPER software and other such products related to patient classification and billing, so as to ensure that they reflect the most up to date codes possible. Beginning with the updates for FY 2020, we apply nonsubstantive changes to the ICD–10 codes included on the PDPM code mappings and lists through a subregulatory process consisting of posting updated code mappings and lists on the PDPM website at *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/SNFPPS/PDPM.* Such nonsubstantive changes are limited to those specific changes that are necessary to maintain consistency with the most current ICD–10 medical code data set. On the other hand, substantive changes, or those that go beyond the intention of maintaining consistency with the most current ICD–10 medical code data set, will be proposed through notice and comment rulemaking. For instance, changes to the assignment of a code to a comorbidity list or other changes that amount to changes in policy are considered substantive changes for which we would undergo notice and comment rulemaking.

This year's proposed rule (86 FR 19984–19985) proposed several changes to the PDPM ICD–10 code mappings and lists. We proposed the following changes:

On October 1, 2020 two ICD–10 codes representing types of sickle-cell disease; D57.42 ''Sickle-cell thalassemia beta zero without crisis'' and D57.44 ''Sickle-cell thalassemia beta plus without crisis'' took effect and were clinically mapped to the category of ''Medical Management''. However, there are more specific codes to indicate why a patient with sickle-cell disease would require SNF care, and if the patient is not in crisis, this most likely indicates that SNF care is not required. For this reason, we proposed to change the assignment of D57.42 and D57.44 to ''Return to Provider''.

On October 1, 2020, three new ICD–10 codes representing types of esophageal conditions; K20.81 ''Other esophagitis with bleeding'', K20.91, ''Esophagitis, unspecified with bleeding, and K21.01 ''Gastro-esophageal reflux disease with esophagitis, with bleeding'' took effect and were clinically mapped to ''Return to Provider''. Upon review of these codes, we recognize that these codes represent these esophageal conditions with more specificity than originally considered because of the bleeding that is part of the conditions and that they would more likely be found in SNF patients. Therefore, we proposed to change the assignment of K20.81, K20.91, and K21.01 to ''Medical Management'' in order to promote more accurate clinical category assignment.

In December 2020, the CDC announced several additions to the ICD–10 Classification related to COVID–19 that became effective on January 1, 2021. One such code, M35.81 ''Multisystem inflammatory syndrome'', was assigned to ''Non-Surgical Orthopedic/Musculoskeletal''. However, Multisystem inflammatory syndrome can involve more than the musculoskeletal system. It can also involve the gastrointestinal tract, heart, central nervous system, and kidneys. For this reason, we proposed to change the assignment of M35.81 to ''Medical Management'' in order to promote more accurate clinical category assignment.

On October 1, 2020, three new ICD–10 codes representing types of neonatal cerebral infarction were classified as ''Return to Provider.'' These codes were P91.821 ''Neonatal cerebral infarction, right side of brain,'' P91.822, ''Neonatal cerebral infarction, left side of brain,'' and P91.823, ''Neonatal cerebral infarction, bilateral.'' While a neonate is unlikely to be a Medicare beneficiary, this diagnosis could continue to be used later in life hence placing those with this condition in the acute neurologic category. Therefore, we proposed to change the assignment of P91.821, P91.822, and P91.823 to ''Acute Neurologic'' in order to promote more accurate clinical category assignment.

On April 1, 2020, U07.0, ''Vaping-related disorder,'' took effect and was classified as a ''Return to Provider'' code because at the time, ''Vaping-related disorder'' was not considered a code that would be a primary diagnosis during a SNF stay. However, upon further review, we believe that many patients who exhibit this diagnosis require steroids, empiric antibiotics and oxygen for care which could carry over to the post-acute setting. For this reason, we proposed to change the assignment of U07.0 to ''Pulmonary'' classification in order to promote more accurate clinical category assignment.

In the FY 2021 proposed rule (85 FR 20939), we sought comments on additional substantive and nonsubstantive changes that commenters believed were necessary. We received three comments suggesting several changes to the ICD–10 to clinical category mappings. One of those changes was substantive, requiring notice and comment rulemaking. The commenter suggested that the FY 2020 ICD–10 to clinical category mapping of G93.1 ''Anoxic brain damage, not elsewhere classified'' be changed to ''Acute Neurologic'' from ''Return to Provider,'' which we would consider a substantive change. Codes that result in ''Return to Provider'' are codes that cannot be used in I0020B of the MDS because item I0020B is used to establish the primary medical condition that a patient presents with during a SNF stay. Although some codes are considered ''Return to Provider'' for payment purposes, they are still used to support the care and services used for secondary and co-morbidity diagnoses. The ICD–10 code, G93.1 was initially clinically mapped to ''Return to provider'' because ''Anoxic brain damage, not elsewhere classified'' was non-specific and did not fully describe a patient's deficits and may not have been an acute condition. However, upon further review, our clinicians determined that although this may not be an acute condition, ''Anoxic brain damage, not elsewhere classified'' would still likely result in a need for SNF care and is similar to conditions such as ''Compression of the brain'', ''Cerebral edema'', and ''encephalopathy'', which are mapped into the ''Acute Neurologic'' category. Therefore, we proposed to change the

assignment of G93.1 ''Anoxic brain damage, not elsewhere classified'' to ''Acute Neurologic''.

We invited comments on the proposed substantive changes to the ICD–10 code mappings discussed previously, as well as comments on additional substantive and non-substantive changes that commenters believe are necessary.

The following is a summary of the public comments received on the proposed revisions to the Technical Updates to PDPM ICD–10 Mappings and our responses:

Comment: Several commenters stated that they support the overall effort to improve accuracy and clarity within PDPM. One commenter specifically notd their appreciation for the change to the PDPM mapping for G93.1 ''Anoxic brain damage, not elsewhere classified'' from ''Return to provider'' to ''Acute neurologic''. Commenters explained that they treat many patients with this ICD–10 diagnosis and the proposed change would better compensate for these services. Another commenter supported the proposed change to the PDPM mapping for K20.81 ''Other esophagitis with bleeding'', K20.91, ''Esophagitis, unspecified with bleeding, and K21.01 ''Gastro-esophageal reflux disease with esophagitis, with bleeding'' from ''Return to provider'' to ''Medical management''.

Response: We appreciate the positive comments we received that supported our efforts to more accurately map several diagnoses under PDPM. We agree with the comments regarding the remapping of G93.1 to ''Acute neurologic'' and K20.81 ''Other esophagitis with bleeding'', K20.91, ''Esophagitis, unspecified with bleeding, and K21.01 ''Gastro-esophageal reflux disease with esophagitis, with bleeding'' to ''Medical management' as well as the proposal to remap M35.81 ''Multisystem inflammatory syndrome;'' P91.821 ''Neonatal cerebral infarction, right side of brain;'' P91.822 ''Neonatal infarction, left side of brain;'' P91.823 ''Neonatal cerebral infarction, bilateral;'' U07.0 ''Vaping-related disorder;'' and G93.1 ''Anoxic brain damage, not elsewhere classified.'' Like the commenters, we believe that remapping will allow for more accurate payment for these diagnoses.

Comment: One commenter did not support the proposal to change mapping of D57.42 ''Sickle-cell thalassemia beta zero without crisis'' and D57.44 ''Sickle-cell thalassemia beta plus without crisis'' from Medical Management to Return to Provider. They stated an understanding that in some cases, there may be a more specific ICD–10 code that may be available, if supported by the physician. However, they stated that residents who have been diagnosed with only D57.42 or D57.44 and not a further specified code may still require a skilled level of care in the SNF for this condition. They stated that since a particular diagnosis, in and of itself, cannot meet the criteria of a skilled level of care, they stated it would be appropriate to continue to map D57.42 and D57.44 to the Medical Management clinical category.

Response: As the commenter explained, a diagnosis, in and of itself, may not meet the criteria of a skilled level of care. We agree with that notion. Therefore, we continue to believe that the diagnosis codes of only D57.42 or D57.44 do not provide enough specific information to be the primary diagnosis used for payment. If there is a symptom or condition that is a result of this diagnosis, that symptom or condition should be coded on the MDS and would be able to be mapped for PDPM payment. We would note that there is no limitation on which ICD–10 diagnoses a provider can include on the MDS 3.0. However, there are specific diagnoses which are more appropriate for PDPM mapping and are used for payment as the primary diagnosis under PDPM.

Comment: One commenter suggested additional changes to the ICD–10 code mappings and comorbidity lists that were outside the scope of this rulemaking. As mentioned previously, this commenter stated their support for changing K20.81, K20.91, and K21.01 from the ''Return to Provider'' mapping to ''Medical Management.'' This commenter also requested that we also consider remapping the following similar diagnosis codes that frequently require SNF skilled care, from Return to Provider to Medical Management: K22.11 ''Ulcer of esophagus with bleeding'', K25.0 ''Acute gastric ulcer with hemorrhage'', K25.1''Acute gastric ulcer with perforation'', K25.2 ''Acute gastric ulcer with both hemorrhage and perforation'', K26.0 ''Acute duodenal ulcer with hemorrhage'', K26.1 ''Acute duodenal ulcer with perforation'', K26.2 ''Acute duodenal ulcer with both hemmhorage and perforation'', K27.0 ''Acute peptic ulcer, site unspecified with hemorrhage'', K27.1 ''Acute peptic ulcer, site unspecified with perforation'', K27.2 ''Acute peptic ulcer, site unspecified with both hemorrhage and perforation'', K28.0 ''Acute gastrojejunal ulcer with hemorrhage'', K28.1 ''Acute gastrojejunal ulcer with perforation'', K28.2 ''Acute gastrojejunal ulcer with both hemorrhage and perforation'', and K29.01 ''Acute gastritis with bleeding.''

They also requested that we consider remapping M62.81 ''Muscle weakness (generalized)'' from Return to Provider to Non-orthopedic Surgery with the rationale that frail elderly beneficiaries are often admitted to the SNF following hospitalization for a significant infection (for example, pneumonia, COVID–19, urinary tract infection, other respiratory infection). This commenter explained that there is currently no sequela or late-effects ICD–10 code available when such beneficiaries require skilled nursing and therapy due to the late effects of the resolved infection. The active infection may no longer exist, but muscle weakness is often the primary diagnosis the physician identifies as requiring skilled care for these frail elderly beneficiaries. Additionally, this commenter asked that we consider remapping R62.7 ''Adult failure to thrive'' from Return to Provider to Medical Management. According to this commenter, physicians often diagnose adult failure to thrive when a resident has been unable to have oral intake sufficient for survival. Typically, this diagnosis is appended when the physician has determined that a feeding tube should be considered to provide sufficient intake for survival. According to the commenter, it would then appropriately become the primary diagnosis for a skilled stay.

Response: We note that the changes suggested by the commenter are outside the scope of this rulemaking, and will not be addressed in this rule. We will further consider the suggested changes to the ICD–10 code mappings and comorbidity lists and may implement them in the future as appropriate. To the extent that such changes are non-substantive, we may issue them in a future subregulatory update if appropriate; however, if such changes are substantive changes, in accordance with the update process established in the FY 2020 SNF PPS final rule, such changes must undergo full notice and comment rulemaking, and thus may be included in future rulemaking. See the discussion of the update process for the ICD–10 code mappings and lists in the FY 2020 SNF PPS final rule (84 FR 38750) for more information.

After considering public comments, we are finalizing the revisions as proposed.

C. Recalibrating the PDPM Parity Adjustment

1. Background

On October 1, 2019, we implemented the Patient Driven Payment Model (PDPM) under the SNF PPS, a new case-mix classification model that replaced the prior case-mix classification model, the Resource Utilization Groups, Version IV (RUG–IV). As discussed in the FY 2019 SNF PPS final rule (83 FR 39256), as with prior system transitions, we proposed and finalized implementing PDPM in a budget neutral manner. This means that the transition to PDPM, along with the related policies finalized in the FY 2019 SNF PPS final rule, were not intended to result in an increase or decrease in the aggregate amount of Medicare payment to SNFs. We believe ensuring parity is integral to the process of providing ''for an appropriate adjustment to account for case mix'' that is based on appropriate data in accordance with section 1888(e)(4)(G)(i) of the Act. Section V.I. of the FY 2019 SNF PPS final rule (83 FR 39255 through 39256) discusses the methodology that we used to implement PDPM in a budget neutral manner. Specifically, we multiplied each of the PDPM case-mix indexes (CMI) by an adjustment factor that was calculated by comparing total payments under RUG–IV, using FY 2017 claims and assessment data (the most recent final claims data available at the time), and what we expected total payments would be under the then proposed PDPM based on that same FY 2017 claims and assessment data. In the FY 2020 SNF PPS final rule (84 FR 38734 through 38735), we finalized an updated standardization multiplier and parity adjustment based on FY 2018 claims and assessment data. Through this comparison, and as discussed in the FY 2020 SNF PPS final rule, this analysis resulted in an adjustment factor of 1.46, by which all the PDPM CMIs were multiplied so that total estimated payments under PDPM would be equal to total actual payments under RUG–IV, assuming no changes in the population, provider behavior, and coding. By multiplying each CMI by 1.46, the CMIs were inflated by 46 percent in order to achieve budget neutrality.

A similar type of adjustment was used when we transitioned from RUG–III to RUG–IV in FY 2011. However, as discussed in the FY 2012 SNF PPS final rule (76 FR 48492 through 48500), we observed that once actual RUG–IV utilization data became available, the actual RUG–IV utilization patterns differed significantly from those we had projected using the historical data that grounded the RUG–IV parity adjustment. As a result, in the FY 2012 SNF PPS final rule, we used actual FY 2011 RUG–IV utilization data to recalibrate the RUG–IV parity adjustment. Based on the use of FY 2011 RUG–IV utilization data, we decreased the RUG–IV parity adjustment applied to the nursing CMIs for all RUG–IV therapy groups from an adjustment factor of 61 percent to an adjustment factor of 19.84 percent (while maintaining the original 61 percent total nursing CMI increase for all non-therapy RUG–IV groups). As a result of this recalibration, FY 2012 SNF PPS rates were reduced by 12.5 percent, or $4.47 billion, in order to achieve budget neutrality under RUG–IV prospectively.

Since PDPM implementation, we have closely monitored PDPM utilization data to ascertain, among other things, if the PDPM parity adjustment provided for a budget neutral transition to this new case-mix classification model. Similar to what occurred in FY 2011 with RUG–IV implementation, we have observed significant differences between expected SNF PPS payments and case-mix utilization, based on historical data, and the actual SNF PPS payments and case-mix utilization under PDPM, based on FY 2020 data. As a result, it would appear that rather than simply achieving parity, the FY 2020 parity adjustment may have inadvertently triggered a significant increase in overall payment levels under the SNF PPS. We believed that, based on the data from this initial phase of PDPM, a recalibration of the PDPM parity adjustment may be warranted to ensure that the adjustment serves its intended purpose to make the transition between RUG–IV and PDPM budget neutral.

However, we also acknowledged in the proposed rule that the pandemic-related PHE for COVID–19, which began during the first year of PDPM and has continued into at least part of FY 2021, has had a likely impact on SNF PPS utilization data. Further, following the methodology utilized in calculating the initial parity adjustment, we typically would use claims and assessment data for a given year to classify patients under both the current system and the prior system to compare aggregate payments and determine an appropriate adjustment factor to achieve parity. When we performed a similar recalibration of the RUG–IV parity adjustment, for example, we used data from FY 2011, the first year of RUG–IV implementation, as the basis for recalibrating the RUG–IV parity adjustment. However, in addition to the aforementioned potential issues with the FY 2020 SNF utilization data arising from the PHE for COVID–19, we were concerned that given the significant differences in both patient assessment requirements and payment incentives between RUG–IV and PDPM, using the same methodology we have used in the past to calculate a recalibrated PDPM parity adjustment could lead to a potentially inaccurate recalibration.

As described in the FY 2022 SNF proposed rule, we presented some of the results of our PDPM data monitoring efforts and a potential recalibration methodology intended to address the issues presented above. First, it was important to provide transparency on the observed impacts of PDPM implementation, as we believed there have been significant changes observed in SNF utilization that are tied strictly to PDPM and not the PHE for COVID–19. Second, we wished to make clear why we believed that the typical methodology for recalibrating the parity adjustment may not provide an accurate recalibration under PDPM. Finally, we viewed this as an opportunity to seek comment on a path forward for recalibrating the PDPM parity adjustment to ensure that PDPM is implemented in a budget neutral manner, as intended.

2. FY 2020 Changes in SNF Case-Mix Utilization

FY 2020 was a year of significant change under the SNF PPS. In addition to implementing PDPM, a national PHE for COVID–19 was declared. With the announcement of the PHE for COVID–19, we also announced a number of waivers that impacted SNF operations and the population of Medicare beneficiaries who were able to access the Part A SNF benefit. Most notably, under authority granted us by section 1812(f) of the Act, we issued a waiver of section 1861(i) of the Act, specifically the requirement that in order for a SNF stay to be covered by Medicare, a beneficiary must have a prior inpatient hospital stay of not less than 3 consecutive days before being admitted to the Part A SNF stay. Additionally, this waiver also allowed certain beneficiaries renewed SNF coverage without first having to start a new benefit period. The section 1812(f) waiver, particularly the component that permits beneficiaries to access the Part A SNF benefit without a prior hospitalization, allowed beneficiaries who would not typically be able to access the Part A SNF benefit to receive a Part A covered SNF stay (for example, long term care nursing home patients without any prior hospitalization). A key aspect of our suggested potential methodology for recalibrating the PDPM

parity adjustment involved parsing out the impact of these waivers and the different population of beneficiaries that had access to the SNF benefit as result of these waivers from the population of beneficiaries that would have been admitted to SNFs subsequent to PDPM implementation without these waivers, as well as differences in the type of care these patients received.

We noted that while the PHE for COVID–19 clearly had impacts on nursing home care protocols and many other aspects of SNF operations, the relevant issue for pursuing a recalibration of the PDPM parity adjustment is whether or not these changes caused the SNF case-mix distribution to be distinctly different from what it would have been were it not for the PHE for COVID–19. In other words, while different people were able to access the Part A SNF benefit than would typically be able to do so, the issue was whether or not the relative percentage of beneficiaries in each PDPM group was different than what those percentages would have been were it not for the PHE for COVID–19 and related waivers. We solicited comments on whether and how stakeholders believed that the PHE for COVID–19 impacted the distribution of patient case-mix.

In the proposed rule, we acknowledged the impact of COVID–19 on SNF utilization data by removing those using a PHE-related waiver and those with a COVID–19 diagnosis from our data set. In FY 2020, only approximately 9.8 percent of SNF stays included a COVID–19 ICD–10 diagnosis code either as a primary or secondary diagnosis, while 15.6 percent of SNF stays utilized a section 1812(f) waiver (with the majority of these cases using the prior hospitalization waiver), as identified by the presence of a ''DR'' condition code on the SNF claim. As compared to prior years, when approximately 98 percent of SNF beneficiaries had a qualifying prior hospital stay, approximately 87 percent of SNF beneficiaries had a qualifying prior hospitalization in FY 2020. These general statistics are important, as they highlight that while the PHE for COVID–19 certainly impacted many aspects of nursing home operations, the overwhelming majority of SNF beneficiaries entered into Part A SNF stays in FY 2020 as they would have in any other year; that is, without using a PHE-related waiver, with a prior hospitalization, and without a COVID–19 diagnosis.

Our data analysis found that even after removing those using a PHE-related waiver and those with a COVID–19 diagnosis from our data set, the observed inadvertent increase in SNF payments since PDPM was implemented was approximately the same. This finding suggests that the significant changes observed in SNF utilization are tied strictly to PDPM and not the PHE for COVID–19, as the ''new'' population of SNF beneficiaries (that is, COVID–19 patients and those using a section 1812(f) waiver) did not appear to be the cause of the increase in SNF payments after implementation of PDPM.

Moreover, we presented evidence that PDPM alone impacted certain aspects of SNF patient classification and care provision. For example, through FY 2019, SNF patients received an average of approximately 91 therapy minutes per day. Beginning concurrently with PDPM implementation (and well before the onset of the pandemic), the average number of therapy minutes SNF patients received per day dropped to approximately 62 minutes, a decrease of over 30 percent. Similarly, we also observed an increase in non-individualized modes of therapy provision beginning with PDPM implementation. While the percentage of SNF stays that included concurrent or group therapy was approximately 1 percent for each of these therapy modes prior to FY 2020, these numbers rose to approximately 32 percent and 29 percent, respectively, concurrent with PDPM implementation. Notably, when the PHE for COVID–19 was declared in April 2020, these numbers then dropped to 8 percent and 4 percent, respectively, highlighting an impact of the PHE for COVID–19 on SNF care provision and utilization.

We also noted that while the increases in concurrent and group therapy utilization were anticipated prior to PDPM implementation based on comments on the FY 2019 and FY 2020 SNF PPS proposed rules, we maintain the belief that the unique characteristics and goals of each SNF patient should drive patient care decisions and we did not identify any significant changes in health outcomes for SNF patients due to PDPM implementation. For example, we observed no significant changes in the percentage of stays with falls with major injury, the percentage of stays ending with Stage 2–4 or unstageable pressure ulcers or deep tissue injury, the percentage of stays readmitted to an inpatient hospital setting within 30 days of SNF discharge, or other similar metrics. As we stated in the FY 2020 SNF PPS final rule (84 FR 38748), we believe that financial motives should not override the clinical judgment of a therapist or therapy assistant to provide less than appropriate therapy, and we will continue to monitor these and other metrics to identify any adverse trends accompanying the implementation of PDPM.

These changes in therapy provision highlight the reasons we believed that the typical methodology for recalibrating a parity adjustment would not be appropriate in the context of PDPM and may lead to an overcorrection. As discussed previously in this final rule and in the FY 2012 SNF PPS final rule (76 FR 26371), we would typically utilize claims and assessment data from a given period under the new payment system, classify patients under both the current and prior payment model using this same set of data, compare aggregate payments under each payment model, and calculate an appropriate adjustment factor to achieve budget neutrality. However, given the significant changes in therapy provision since PDPM implementation, we found that using FY 2020 patient assessment data collected under PDPM would lead to a significant underestimation of RUG–IV case mix for purposes of determining what aggregate payments would have been under RUG–IV for the same period.

We invited comments on the information presented above, as well as on the potential impact of using the reported FY 2020 patient assessment data from the MDS to reclassify SNF beneficiaries under RUG–IV, consistent with the same type of recalibration methodology we have used for prior system transitions.

3. Methodology for Recalibrating the PDPM Parity Adjustment

In this section, we discuss the methodology we considered in the FY 2022 proposed rule for recalibrating the PDPM parity adjustment. Table 23 provides the expected and actual average PDPM CMI expected for each of the PDPM rate components based on data from FY 2019 and FY 2020. First, we calculated the expected average CMI for each component by summing the expected PDPM CMI for each day of service in FY 2019 and then dividing by the total number of days of service in FY 2019. Next, we provided two separate calculations for the actual average PDPM CMI, both for the full SNF population and for the SNF population after exclusions due to COVID (henceforth referred to as the ''subset population''), by summing the CMI for each day of service in FY 2020 and then divided this by the total number of days of service in FY 2020. As discussed above, we excluded SNF stays where the patient was diagnosed with COVID–

19 or the stay utilized a PHE for COVID–19 related waiver, as identified by the presence of a ''DR'' condition code on the associated SNF claim.

TABLE 23: Average Case-Mix Index, Expected and Actual, by Component

	Expected CMI (FY 2019 Estimate)	Actual CMI (FY 2020)	Actual CMI (FY 2020 without DR or COVID)
Component	Average CMI	Average CMI	Average CMI
PT	1.53	1.50	1.52
OT	1.52	1.51	1.52
SLP	1.39	1.71	1.67
Nursing	1.43	1.67	1.62
NTA	1.14	1.20	1.21

The results presented in Table 23 show that the average CMI for both the full and subset FY 2020 populations was slightly lower than expected for the PT and OT rate components, and much higher than expected for the SLP, Nursing, and NTA components. We believed that the significant increases of 22.6 percent, 16.8 percent, and 5.6 percent in average case-mix, respectively, for the full FY 2020 SNF population was primarily responsible for the inadvertent increase in spending under PDPM. Further, given that we observed similar increases in the average CMI for these components in the subset FY 2020 SNF population, we believed that these increases in average case-mix for these components were the result of PDPM and not the PHE for COVID–19. We invited comments on this approach and the extent to which commenters believed that the PHE for COVID–19 may have impacted the PDPM case-mix distribution in ways not captured in Table 23 or in the discussion provided here.

Historically, our basic methodology for recalibrating the parity adjustment has been to compare total payments under the new case-mix model with what total payments would have been under the prior case-mix model, were the new model not implemented. In the context of the PDPM, this meant comparing total FY 2020 payments under PDPM to what FY 2020 payments would have been under RUG–IV if PDPM were not implemented. In order to calculate expected total payments under RUG–IV, we used the percentage of stays in each RUG–IV group in FY 2019 and multiplied these percentages by the total number of FY 2020 days of service. We then multiplied the number of days for each RUG–IV group by the RUG–IV per diem rate, which we obtained by inflating the FY 2019 SNF PPS RUG–IV rates by the FY 2020 market basket update factor. The total payments under RUG–IV also accounted for the AIDS add-on under RUG–IV and a provider's FY 2020 urban or rural status. In order to calculate the actual total payments under PDPM, we used data reported on FY 2020 claims. Specifically, we used the Health Insurance Prospective Payment System (HIPPS) code on the SNF claim to identify the patient's case-mix assignment and associated CMIs, utilization days on the claim to calculate stay payments and the variable per diem adjustment, the presence of an HIV diagnosis on the claim to account for the PDPM AIDS add-on, and a provider's urban or rural status. As with the analysis for Table 23, we calculated total payments both for the full and subset FY 2020 SNF populations.

We believed that this methodology provided a more accurate representation of what RUG–IV payments would have been in FY 2020, were it not for the change in payment incentives and care provision precipitated by PDPM implementation, than using data reported under PDPM to reclassify these patients under RUG–IV. In particular, given the reduction in therapy utilization under PDPM as compared to RUG–IV, using the therapy utilization data reported under PDPM to reclassify SNF patients back into RUG–IV groups would produce a case-mix distribution that would be significantly different from the RUG–IV case-mix distribution we would have expected were it not for PDPM implementation. Since the reduction in therapy would lead to a reduction in the RUG–IV case-mix assignments (for example, Ultra-High and Very-High Rehabilitation assignments are not nearly as prevalent using PDPM-reported data as they are using data that existed prior to PDPM), this would lead to an underestimation of what RUG–IV payments would have been in FY 2020. This, in turn, would lead to an overcorrection in recalibrating the parity adjustment due to the low estimated total RUG–IV payments. Additionally, given the significant changes in the patient assessment schedule, specifically the removal of the Change of Therapy Other Medicare Required Assessment, we cannot know if the patient would continue to remain classified in the RUG–IV group into which the patient classified on the 5-day assessment beyond that assessment window. In other words, without having an interim assessment between the 5-day assessment and the patient's discharge from the facility, we would be unable to determine if the RUG–IV group into which the patient classified on the 5-day assessment changed during the stay, or if the patient continued to receive an amount of therapy services consistent with the initial RUG–IV classification. As a result, using reported data under PDPM could lead to a reclassification of patients under RUG–IV that is not consistent with how patients would have been classified under RUG–IV if PDPM had not been implemented. As such, we believed that using the FY 2019 RUG–IV case-mix distribution as a proxy for what the RUG–IV case-mix distribution would have been in FY 2020 were it not for PDPM implementation provides a more accurate calculation of what total RUG–IV payments would have been during FY 2020 absent PDPM implementation.

Our analysis identified a 5.3 percent increase in aggregate spending under PDPM as compared to expected total payments under RUG–IV for FY 2020

when considering the full SNF population, and a 5 percent increase in aggregate spending under PDPM for FY 2020 when considering the subset population. Although these results are similar, in light of the potential differences in the PDPM case-mix distribution that may have been precipitated by the admission of patients diagnosed with COVID–19 and patients whose stays utilized a PHE-related waiver, we believe it would be more appropriate to pursue a recalibration using the subset population. Since the initial increase to the PDPM CMIs to achieve budget neutrality applied equally across all case-mix adjusted components, we believed it would be appropriate, in the event an adjustment is made, to adjust the CMIs across all such components in equal measure. Using the methodology described above, the resultant PDPM parity adjustment factor would be lowered from 46 percent to 37 percent for each of the PDPM case-mix adjusted components. If we applied this methodology for FY 2022, we estimated a reduction in SNF spending of 5 percent, or approximately $1.7 billion.

Based on the above discussion and analysis, we described a potential path towards a recalibration of the PDPM parity adjustment. We invited comments on our methodology, particularly on the use of the FY 2019 RUG–IV case-mix distribution to calculate expected FY 2020 SNF payments and on using the subset FY 2020 SNF population.

As we noted in the FY 2012 SNF PPS final rule (76 FR 48493), we believe it is imperative that we act in a well-considered but expedient manner once excess payments are identified, as we did in FY 2012. However, despite the importance of ensuring that PDPM is budget neutral going forward, we acknowledged that applying such a significant reduction in payments in a single year without time to prepare for the reduction in revenue could create a financial burden for providers. We therefore considered two potential mitigation strategies to ease the transition to prospective budget neutrality in the event an adjustment is finalized: Delayed implementation and phased implementation.

With regard to a delayed implementation strategy, this would mean that we would implement the reduction in payment, or some portion of the reduction in payment if combined with a phased implementation approach described below, in a later year than the year in which the reduction is finalized. For example, considering the 5 percent reduction discussed above, if this reduction was finalized in FY 2022 with a 1 year delayed implementation, this would mean that the full 5 percent reduction would be prospectively applied to the PDPM CMIs in FY 2023. If the reduction was finalized in FY 2022 with a 2 year delayed implementation, then the full 5 percent reduction in the PDPM CMIs would be applied prospectively beginning in FY 2024. This type of strategy on its own does not serve to mitigate the overall amount of the reduction in a single year, but rather serves to provide facilities with time to prepare for the impending reduction in payments. We solicited comments on whether stakeholders believe that, in the event we finalize the parity adjustment recalibration, we should finalize this recalibration with a delayed implementation. Additionally, to the extent that stakeholders believe that a delayed implementation would be warranted, we solicited comments on the appropriate length of the delay.

With regard to a phased implementation strategy, this would mean that the amount of the reduction would be spread out over some number of years. Such an approach helps to mitigate the impact of the reduction in payments by applying only a portion of the reduction in a given year. For example, if we were to use a 2-year phased implementation approach to the 5 percent reduction discussed above, this would mean that the PDPM CMIs would be reduced by 2.5 percent in the first year of implementation and then reduced by the remaining 2.5 percent in the second and final year of implementation. So, for example, if this adjustment was finalized for FY 2022, then the PDPM CMIs would be reduced by 2.5 percent in FY 2022 and then reduced by an additional 2.5 percent in FY 2023. We note that the number of years for a phased implementation approach could be as little as 2 years but as long as necessary to appropriately mitigate the yearly impact of the reduction. For example, we could implement a 5-year phased approach for this reduction, which would apply a one percent reduction to the PDPM CMIs each year for 5 years. We solicited comments on the need for a phased implementation approach to recalibrating the PDPM parity adjustment, as well as on the appropriate length of such an approach.

We could also use a combination of both mitigation strategies. For example, we could finalize a 2 year phased approach with a 1 year delayed implementation. Using FY 2022 as the hypothetical year in which such an approach could be finalized, this would mean that there would be no reduction to the PDPM CMIs in FY 2022, a 2.5 percent reduction to the PDPM CMIs in FY 2023, and then a 2.5 percent reduction in the PDPM CMIs in FY 2024. We solicited comments on the possibility of combining these approaches and what stakeholders believe would be appropriate to mitigate the impact of the reduction in SNF PPS payments.

We noted that for any of these options, the adjustment would be applied prospectively, and the case mix indexes would not be adjusted to account for deviations from budget neutrality in years before the payment adjustments are implemented.

We invited comments on the methodology described above for recalibrating the PDPM parity adjustment and the strategies described above for mitigating the impact of implementing such an adjustment, in the event we finalize a recalibration.

Comment: The majority of commenters strongly objected to our methodology and the possibility of finalizing the recalibration in FY 2022 during the COVID–19 PHE. We received comments about this issue both from individual commenters and multiple letter writing campaigns. Commenters suggested that FY 2020 data was not representative because PDPM was only in place for 5 months, from October 2019 to February 2020, prior to the beginning of the PHE. They outlined several ways that the PHE affected FY 2020 data in ways not accounted for by our subset population methodology, which excluded patients with a COVID–19 diagnosis or who utilized a PHE-related disaster waiver. Their critiques of our methodology fall into two categories: That we did not fully account for the acuity of patients with COVID–19 and that we did not fully account for the overall effect of the PHE across all patients.

First, commenters were concerned that our analysis did not account for the impact of COVID–19 on overall patient case-mix and acuity. Some commenters suggested that we may have missed COVID–19 cases from the early months of the PHE because there was no COVID–19 specific diagnosis code available before April 2020 and because providers were unaware of or confused about waiver utilization. Additionally, the well-documented shortage of COVID–19 testing led to SNFs being unable to confirm and report COVID–19 cases despite higher than average caseloads in upper respiratory infections and associated increases in patient acuity. In light of this, one commenter suggested that we analyze the FY 2020 data for a higher-than-

expected burden of upper respiratory infection cases and exclude these sicker patients from the parity adjustment analysis. Finally, commenters were concerned that PDPM did not fully capture clinically appropriate sequelae or adequately reimburse intensive nursing care provided to COVID–19 patients who were cohorted together instead of in a single room.

Second, commenters stated that the PHE raised the clinical complexity of all residents regardless of COVID–19 illness or diagnosis, therefore skewing the case-mix data for FY 2020. Because many providers chose to halt elective surgeries during a portion of the PHE, the residents admitted were the most acute who could not be cared for at home. Limitations regarding visitation led to higher levels of mood distress, cognitive decline, mobility decline, change in appetite, weight loss requiring diet modifications, and compromised skin integrity. Occupancy dropped significantly compared to pre-pandemic levels (many commenters reported an approximate 20 percent decrease) and commenters believe it could take up to 2 or 3 years to return to a pre-pandemic level census. One commenter expressed concern with the accuracy of the CMIs due to having a smaller sample size due to excluding COVID cases, stating that these factors would have impacted average CMI calculations and would not be representative of an average SNF yearly census.

Overall, the majority of commenters agreed that it was difficult to assess true PDPM case-mix distribution due to only a very short period before the PHE, and therefore believed that a longer time period of data outside of a PHE environment is necessary to determine whether a parity adjustment is required. They urged CMS to take more time for deliberation and utilize a period of data outside of a PHE environment, defined by one commenter as beginning 90 days after the end of the PHE and continuing for one year thereafter.

Some commenters supported the analytic approach we described in the proposed rule and concurred with the need for a parity adjustment. While MedPAC recommended proceeding cautiously and making no update for FY 2022, they found our data analysis approach to be reasonable and urged CMS to keep an account of overpayments that would have been made in establishing future updates. Several commenters indicated that they would support a future parity adjustment, if warranted, if CMS combines delayed implementation with a phased-in approach. One commenter recommended proceeding with the parity adjustment for FY 2022 due primarily to behavioral changes exhibited by SNFs at the outset of PDPM, such as the reduction in therapy services provided to SNF patients.

Response: We thank the commenters for their feedback. In light of these comments, as well as the importance of addressing any existing overpayments under the SNF PPS, we intend to utilize these comments to refine the data we have collected in developing a proposed methodology that will be included in the FY 2023 SNF PPS Proposed Rule.

Comment: Several commenters made suggestions for revisions to our methodology and opposed the possibility of finalizing the recalibration in FY 2022 for reasons unrelated to the COVID–19 PHE. Some commenters pointed out that our analysis did not account for the effect of CMS' instruction to assess all patients anew in October 2019 using the PDPM MDS assessment, which would likely have elevated NTA scores due to restarting the stay at the highest payment level, even though some patients assessed may have been in the middle or end of their Medicare Part A coverage. One commenter supported our methodology, stating that it would be inappropriate to attempt to reclassify the data set associated with the FY 2020 SNF population using the RUG–IV model, given the significant differences between the two and the changes implemented to the patient assessment schedule.

Some commenters suggested that budget neutrality may not be an attainable goal because less attention was paid to diagnosis coding under RUG–IV. One commenter stated that the exact opposite occurred of the assumption stated in the proposed rule regarding no changes in the population, provider behavior, and coding, as PDPM represented a significant change in how nursing homes should manage and document care for Medicare Part A residents. The same commenter stated that by transitioning to a system where therapy minutes primarily drove reimbursement to a system where a more holistic coding approach established payment, one would expect more accurate coding. This change is better for patient care and does not indicate that conditions such as depression and swallowing difficulties were not treated prior to PDPM, but rather indicates providers are demonstrating more accurate documentation to support the care already being given for these conditions.

Response: We thank the commenters for their feedback and will take these recommendations into consideration for the FY 2023 SNF PPS proposed rule. However, we remind commenters that the methodology used to identify the magnitude of the adjustment necessary to achieve parity does not rely on the actual dollar amounts paid under PDPM, but rather a comparison between expected SNF PPS payments, based on historical case-mix utilization data under RUG–IV, to SNF PPS payments based on actual case-mix utilization data collected after PDPM implementation.

Comment: Some commenters stated that expenditures for their facilities did not support a 5 percent potential parity adjustment. One commenter calculated a 4.5 percent increase, inclusive of the 2.8 percent market basket increase, in overall payment under PDPM as compared to the RUG–IV. Another commenter stated that the PDPM budget neutrality adjustment did not take into account the 2 percent reduction (60 percent of which would be available to be earned back as a value-based incentive payment) to be put in the Medicare trust fund from the SNF VBP program.

Response: We appreciate these comments. As described in the proposed rule, our methodology included the subset population of SNF beneficiaries without a COVID–19 diagnosis or a PHE-related disaster waiver, across all facilities. We understand that there may be variation between facilities, though the parity adjustment is calculated and applied at a systemic level to all facilities paid under the SNF PPS. We emphasize that budget neutrality refers only to the transition between case-mix classification models (in this case, from RUG–IV to PDPM) and is not intended to include unrelated SNF policies such as the market basket increase or the SNF VBP program.

Comment: One commenter supported delaying the PDPM parity adjustment due to the proposed substantive changes to the ICD–10 diagnosis code mapping, stating that these changes may have a significant impact on the accuracy of patient classification and on payment amounts if finalized.

Response: We thank the commenter for this feedback and will take this recommendation into consideration for the FY 2023 SNF PPS proposed rule.

Comment: The majority of commenters supported combining both mitigation strategies of delayed implementation of 2 years and a gradual phase-in of no more than 1 percent per year. MedPAC supported delayed implementation, but did not believe a phased-in approach is warranted given

the high level of aggregate payment to SNFs.

Response: We thank the commenters for their feedback and will take these recommendations into consideration for the FY 2023 SNF PPS proposed rule.

Comment: Some commenters made recommendations to revise the methodology for applying the recalibrated parity adjustment factor, after it is recalculated in light of the comments on the proposed rule. Several commenters disagreed with adjusting the CMIs across all case-mix adjusted components in equal measure, suggesting that this approach would harm patient care by further reducing therapy minutes. Instead, the commenters recommended adjusting only the CMIs for those PDPM components that drive the unintended increase observed under PDPM. According to data provided in the proposed rule, these would be the SLP, Nursing, and NTA components, not the PT or OT components. One commenter further recommended that the bottom four PDPM SLP groups (A, B, C, and D) remain unadjusted as those reimbursement levels are already very low. Several other commenters disagreed with adjusting the CMIs across all SNFs, instead suggesting that CMS should develop indicators to identify and impose financial penalties on the specific facilities driving the increase.

Response: We thank the commenters for their feedback and will take these recommendations into consideration for the FY 2023 SNF PPS proposed rule.

We thank the commenters for their feedback and will take these suggestions and recommendations into consideration as we consider the best path forward to ensure budget neutrality in the FY 2023 SNF PPS proposed rule. As stated earlier in this section, we believe it is imperative that we act in a well-considered but expedient manner once excess payments are identified. Additionally, as stated earlier in this section, our analysis of FY 2020 data found that even after removing beneficiaries using a PHE-related waiver or with a COVID–19 diagnosis from our data set, the observed inadvertent increase in SNF payments since PDPM was implemented was approximately the same. We will continue to monitor all available data and take that into consideration, in combination with the feedback and recommendations received, for developing the FY 2023 SNF PPS proposed rule.

VII. Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

A. Background and Statutory Authority

The Skilled Nursing Facility Quality Reporting Program (SNF QRP) is authorized by section 1888(e)(6) of the Act, and it applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. Section 1888(e)(6)(A)(i) of the Act requires the Secretary to reduce by 2 percentage points the annual market basket percentage update described in section 1888(e)(5)(B)(i) of the Act applicable to a SNF for a fiscal year, after application of section 1888(e)(5)(B)(ii) of the Act (the productivity adjustment) and section 1888(e)(5)(B)(iii) of the Act, in the case of a SNF that does not submit data in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for that fiscal year. For more information on the requirements we have adopted for the SNF QRP, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429), FY 2017 SNF PPS final rule (81 FR 52009 through 52010), FY 2018 SNF PPS final rule (82 FR 36566 through 36605), FY 2019 SNF PPS final rule (83 FR 39162 through 39272), and FY 2020 SNF PPS final rule (84 FR 38728 through 38820).

B. General Considerations Used for the Selection of Measures for the SNF QRP

For a detailed discussion of the considerations we use for the selection of SNF QRP quality, resource use, or other measures, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46429 through 46431).

1. Quality Measures Currently Adopted for the FY 2022 SNF QRP

The SNF QRP currently has 13 measures for the FY 2022 SNF QRP, which are outlined in Table 24. For a discussion of the factors used to evaluate whether a measure should be removed from the SNF QRP, we refer readers to 42 CFR 413.360(b)(3).

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TABLE 24: Quality Measures Currently Adopted for the FY 2022 SNF QRP

Short Name	Measure Name & Data Source
Resident Assessment Instrument Minimum Data Set (Assessment-Based)	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment/Care Plan	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility Score	Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).
Discharge Mobility Score	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
Change in Self-Care Score	Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).
Discharge Self-Care Score	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
TOH-Provider*	Transfer of Health Information to the Provider Post-Acute Care (PAC).
TOH-Patient*	Transfer of Health Information to the Patient Post-Acute Care (PAC).
Claims-Based	
MSPB SNF	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) (NQF #3481).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

*In response to the public health emergency (PHE) for the Coronavirus Disease 2019 (COVID-19), CMS released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for collection and reporting of the Transfer of Health Information measures for at least two full fiscal years after the end of the PHE.

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C. SNF QRP Quality Measure Proposals Beginning With the FY 2023 SNF QRP

Section 1899B(h)(1) of the Act permits the Secretary to remove, suspend, or add quality measures or resource use or other measures described in sections 1899B(c)(1) and (d)(1) of the Act, respectively, so long as the Secretary publishes in the **Federal Register** (with a notice and comment period) a justification for such removal, suspension or addition. Section 1899B(a)(1)(B) of the Act requires that all of the data that must be reported in accordance with section 1899B(a)(1)(A) of the Act (including resource use or other measure data under section 1899B(d)(1)) be standardized and interoperable to allow for the exchange of the information among post-acute care (PAC) providers and other providers and the use by such providers of such data to enable access to longitudinal information and to facilitate coordinated care.

We proposed to adopt two new measures for the SNF QRP beginning with the FY 2023 SNF QRP: The SNF Healthcare-Associated Infections Requiring Hospitalization measure (SNF HAI) and the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP)[4] measure as an ''other measure'' under section 1899B(d)(1) of the Act. The SNF HAI measure is an outcome measure. The data used to report the SNF HAI measure are standardized and interoperable and would allow providers to exchange this data and compare outcomes across the care continuum and PAC settings. Clinical data captured in every clinical setting informs a resident's current medical care plan, facilitates coordinated care, and improves Medicare beneficiary outcomes. We plan to develop HAI measures in other PAC settings, such as the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program and the Long-Term Care Hospital (LTCH) Quality Reporting Program. The proposed measure supports the CMS Meaningful Measures Initiative through the Making Care Safer by Reducing Harm Caused in the Delivery of Care domain. We have previously solicited feedback on the SNF HAI measure as a future measure for the SNF QRP and received several comments of support as well as a few comments recommending suggestions (84 FR 38765). The measure is described in more detail below.

We proposed the COVID–19 Vaccination Coverage among HCP measure as an ''other'' measure under section 1899B(d)(1) of the Act beginning with the FY 2023 SNF QRP. In accordance with section 1899B(a)(1)(B) of the Act, the data used to calculate this measure are standardized and interoperable. The proposed measure supports the Meaningful Measures domain of Promote Effective Prevention

[4] The measure steward changed the name of the measure from SARS–CoV–2 Vaccination Coverage among Healthcare Personnel to COVID–19 Vaccination Coverage among Healthcare Personnel. There were no changes to the measure itself, other than the name change.

and Treatment of Chronic Disease. We identified the measure concept as a priority in response to the current public health crisis. This process measure was developed with the Centers for Disease Control and Prevention (CDC) to track COVID–19 vaccination coverage among HCP in the SNF setting. This measure is described in more detail below.

In addition, we proposed to update the denominator for one measure, the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure to exclude residents discharged home under the care of an organized home health service or hospice.

1. Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAI) Requiring Hospitalization Quality Measure Beginning With the FY 2023 SNF QRP

a. Background

Monitoring the occurrence of HAIs among SNF residents can provide valuable information about a SNF's quality of care. Although HAIs are not considered ''never events'', or serious adverse errors in the provision of health care services that should never occur, most are preventable as they are often the result of poor processes and structures of care.[5] Evidence suggests there is a wide variation in HAI rates among SNF providers. An analysis of FY 2018 SNF claims indicates a performance gap in HAI rates across SNFs. Among the 14,347 SNFs included in the sample for the analysis, risk-adjusted measure scores ranged from a minimum of 2.19 percent to a maximum of 19.83 percent. Further, a 2014 report from the Office of the Inspector General (OIG) estimated that one in four adverse events among SNF residents are due to HAIs, and more than half of all HAIs are potentially preventable.[6] Typically, HAIs result from inadequate patient management following a medical intervention, such as surgery or device implementation, or poor adherence to protocol and antibiotic stewardship guidelines.[7 8 9] Several provider characteristics are also related to HAIs including staffing levels (for example, high turnover, low staff-to-resident ratios, etc.), facility structure characteristics (for example, national chain membership, high occupancy rates, etc.), and adoption or lack thereof of infection surveillance and prevention policies.[10 11 12 13 14 15] Inadequate prevention and treatment of HAIs is likely to result in poor health care outcomes for residents and wasteful resource use. For example, HAIs are associated with longer lengths of stay, use of higher-intensity care (for example, critical care services and hospital readmissions), increased mortality, and high health care costs.[16 17 18 19] Monitoring SNF HAI rates would provide information about each facility's adeptness in infection prevention and management.

Addressing HAIs in SNFs is particularly important as several factors place SNF residents at high risk for infection, including increased age, cognitive and functional decline, use of indwelling devices, frequent care transitions, and close contact with other resident and healthcare workers.[20 21] Furthermore, in SNFs, COVID–19 has a disproportionate impact on racial and ethnic minorities as well as people living with disabilities.[22 23] Emerging COVID–19 studies reveal higher patient spread due to poor infection control, staff rotations between multiple SNFs, and poor patient COVID–19 screenings.[24 25] An analysis comparing

[5] CMS. (2006). Eliminating Serious Preventable, and Costly Medical Errors—Never Events. Retrieved from *https://www.cms.gov/newsroom/fact-sheets/eliminating-serious-preventable-and-costly-medical-errors-never-events.*

[6] Office of Inspector General. (2014). Adverse events in skilled nursing facilities: National incidence among Medicare beneficiaries. Retrieved from *https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.*

[7] Beganovic, M., & Laplante, K. (2018). Communicating with Facility Leadership; Metrics for Successful Antimicrobial Stewardship Programs (Asp) in Acute Care and Long-Term Care Facilities. Rhode Island medical journal (2013), 101(5) (2018), 45–49.

[8] Cooper, D., McFarland, M., Petrilli, F., & Shells, C. (2019). Reducing inappropriate antibiotics for urinary tract infections in long-term care: A replication study. Journal of Nursing Care Quality, 34(1), 16–21. *http://dx.doi.org/10.1097/NCQ.0000000000000343.*

[9] Feldstein, D., Sloane, P.D., & Feltner, C. (2018). Antibiotic stewardship programs in nursing homes: A systematic review. Journal of the American Medical Directors Association, 19(2), 110–116. *http://dx.doi.org/10.1016/j.jamda.2017.06.019.*

[10] Castle, N., Engberg, J.B., Wagner, L.M., & Handler, S. (2017). Resident and facility factors associated with the incidence of urinary tract infections identified in the Nursing Home Minimum Data Set. Journal of Applied Gerontology, 36(2), 173–194. *http://dx.doi.org/10.1177/0733464815584666.*

[11] Crnich, C.J., Jump, R., Trautner, B., Sloane, P.D., & Mody, L. (2015). Optimizing antibiotic stewardship in nursing homes: A narrative review and recommendations for improvement. Drugs & Aging, 32(9), 699–716. *http://dx.doi.org/10.1007/s40266-015-0292-7.*

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[13] Cooper, D., McFarland, M., Petrilli, F., & Shells, C. (2019). Reducing inappropriate antibiotics for urinary tract infections in long-term care: A replication study. Journal of Nursing Care Quality, 34(1), 16–21. *http://dx.doi.org/10.1097/NCQ.0000000000000343.*

[14] Gucwa, A.L., Dolar, V., Ye, C., & Epstein, S. (2016). Correlations between quality ratings of skilled nursing facilities and multidrug-resistant urinary tract infections. American Journal of Infection Control, 44(11), 1256–1260. *http://dx.doi.org/10.1016/j.ajic.2016.03.015.*

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[16] CMS. (2006). Eliminating Serious Preventable, and Costly Medical Errors—Never Events. Retrieved from *https://www.cms.gov/newsroom/fact-sheets/eliminating-serious-preventable-and-costly-medical-errors-never-events.*

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[21] Office of Disease Prevention and Health Promotion. (2013). Long-term care facilities. In U.S. Department of Health and Human Services, National action plan to prevent health care-associated infections: Road map to elimination (pp. 194–239). Retrieved from *https://health.gov/our-work/health-care-quality/health-care-associated-infections/national-hai-action-plan.*

[22] Chidambaram, P., Neuman T., Garfield R. (2020). Racial and Ethnic Disparities in COVID–19 Cases and Deaths in Nursing Homes. Retrieved from *https://www.kff.org/coronavirus-covid-19/issue-brief/racial-and-ethnic-disparities-in-covid-19-cases-and-deaths-in-nursing-homes/.*

[23] Li Y., Cen X., Temkin-Greener R. (2020). Racial and Ethnic Disparities in COVID–19 Infections and Deaths Across U.S. Nursing Homes. Journal of the American Geriatrics Society, 68(11), 2454–2461. *https://pubmed.ncbi.nlm.nih.gov/32955105/.*

[24] Kimball, A., Hatfield, K.M., Arons, M., James, A., Taylor, J., Spicer, K., Bardossy, A.C., Oakley, L.P., Tanwar, S., Chisty, Z., Bell, J.M., Methner, M., Harney, J., Jacobs, J.R., Carlson, C.M., McLaughlin, H.P., Stone, N., Clark, S., Brostrom-Smith, C., Page, L.C., . . . CDC COVID–19 Investigation Team (2020). Asymptomatic and Presymptomatic SARS–CoV–2 Infections in Residents of a Long-Term Care Skilled Nursing Facility—King County, Washington, March 2020. *MMWR. Morbidity and mortality weekly report, 69*(13), 377–381. *https://doi.org/10.15585/mmwr.mm6913e1.*

[25] McMichael, T.M., Clark, S., Pogosjans, S., Kay, M., Lewis, J., Baer, A., Kawakami, V., Lukoff, M.D., Ferro, J., Brostrom-Smith, C., Riedo, F.X., Russell, D., Hiatt, B., Montgomery, P., Rao, A.K., Currie, D.W., Chow, E.J., Tobolowsky, F., Bardossy, A.C., Oakley, L.P., . . . Public Health—Seattle & King County, EvergreenHealth, and CDC COVID–19

Continued

SNF HAI rates using FY 2019 data with the currently reported rates of COVID–19 in SNFs found that nursing homes with higher HAI rates in FY 2019 also have a higher number of COVID–19 cases.[26] This analysis was presented to the PAC–LTC MAP Workgroup at the January 11th meeting (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94559,* slide 134). We believe this finding supports a relationship not only between this measure and overall HAI prevention and control in SNFs, but also in predicting those SNFs more likely to have higher rates of infection in future pandemics. Several interventions may reduce HAI rates among SNFs, thus improving quality of care. These interventions include the adoption of infection surveillance and prevention policies, safety procedures, antibiotic stewardship, and staff education and training programs.[27] [28] [29] [30] [31] [32] [33]

Additionally, infection prevention and control programs with core components in education, monitoring, and feedback on infection rates from surveillance programs or feedback on infection control practices from audits have been found to be successful interventions for reducing HAIs.[34] The effectiveness of these interventions suggests improvement of HAI rates among SNF residents is possible through modifying provider-led processes and interventions.

The proposed SNF HAI measure uses Medicare fee-for-service (FFS) claims data to estimate the risk-standardized rate of HAIs that are acquired during SNF care and result in hospitalization. Unlike other HAI measures that target specific infections, this measure would target all HAIs serious enough to require admission to an acute care hospital. Given the current COVID–19 public health emergency, we believe this measure would promote patient safety and increase the transparency of quality of care in the SNF setting. This measure also compares SNFs to their peers to statistically separate those that perform better than or worse than each other in infection prevention and management. We believe peer comparison would encourage SNFs to improve the quality of care they deliver.

b. Stakeholder and Technical Expert Panel (TEP) Input

In our development and specification of this measure, we employed a transparent process in which we sought input from stakeholders and national experts and engaged in a process that allowed for pre-rulemaking input, in accordance with section 1890A of the Act.

To meet this requirement, we provided the following opportunities for stakeholder input. Our measure development contractor for the SNF HAI measure convened a Technical Expert Panel (TEP) on May 9, 2019 to obtain expert input on the development of an HAI measure for use in the SNF QRP. The TEP consisted of stakeholders with a diverse range of expertise, including SNF and PAC subject matter knowledge, clinical and infectious disease expertise, patient and family perspectives, and measure development experience. The TEP supported the proposed measure concept and provided substantive input regarding the measure's specifications. Recommendations provided by the TEP included refining the measure's operational definition, exclusion criteria, and HAI ICD–10 diagnosis code list, among other considerations. All recommendations from the TEP were taken into consideration and applied appropriately where feasible. A summary of the TEP proceedings titled SNF HAI Final TEP Report is available on the SNF QRP Measures and Technical Information page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

Following the TEP, our measure development contractor released draft quality measure specifications for public comment on the SNF HAI measure. Stakeholder feedback was solicited on the proposed measure by requesting comment on the CMS Measures Management System Blueprint site. The comment submission period was from September 14, 2020 to October 14, 2020. Comments on the measure varied. Many commenters supported the idea of adopting an HAI measure to improve prevention efforts; however, commenters also offered criticisms about the measure's specifications and implementation. The summary report of the September 14 to October 14, 2020 public comment period titled SNF HAI Public Comment Summary Report is available on the SNF QRP Measures and Technical Information page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

c. Measure Applications Partnership (MAP) Review

Our pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures under Consideration (MUC) List that the Secretary is considering adopting through the Federal rulemaking process for use in Medicare programs. This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list.

We included the SNF HAI measure under the SNF QRP Program in the publicly available ''List of Measures under Consideration for December 21,

Investigation Team (2020). COVID–19 in a Long-Term Care Facility—King County, Washington, February 27–March 9, 2020. *MMWR. Morbidity and mortality weekly report, 69*(12), 339–342. *https://doi.org/10.15585/mmwr.mm6912e1.*

[26] The CMS COVID–19 Nursing Home Dataset used in this analysis was not limited to just the SNF, but applied to the entire nursing home. The study population of the analysis includes Medicare-certified nursing homes providing SNF care.

[27] Office of Inspector General. (2014). Adverse events in skilled nursing facilities: National incidence among Medicare beneficiaries. Retrieved from *https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.*

[28] Beganovic, M., & Laplante, K. (2018). Communicating with Facility Leadership; Metrics for Successful Antimicrobial Stewardship Programs (Asp) in Acute Care and Long-Term Care Facilities. Rhode Island medical journal (2013), 101(5) (2018), 45–49.

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[30] Freeman-Jobson, J.H., Rogers, J.L., & Ward-Smith, P. (2016). Effect of an education presentation on the knowledge and awareness of urinary tract infection among non-licensed and licensed health care workers in long-term care facilities. Urologic Nursing, 36(2), 67–71. *http://dx.doi.org/10.7257/1053-816X.2016.36.2.67* Crnich, C.J., Jump, R., Trautner, B., Sloane, P.D., & Mody, L. (2015). Optimizing antibiotic stewardship in nursing homes: A narrative review and recommendations for improvement. Drugs & Aging, 32(9), 699–716. *http://dx.doi.org/10.1007/s40266-015-0292-7.*

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[34] Lee, M.H., Lee GA, Lee SH, Park YH (2019). Effectiveness and core components of infection prevention and control programmes in long-term care facilities: a systematic review. Retrieved from *https://pubmed.ncbi.nlm.nih.gov/30794854/.*

2020'' (MUC List).[35] The National Quality Forum (NQF)-convened Measure Applications Partnership (MAP) Post-Acute Care/Long-Term Care (PAC–LTC) workgroup met virtually on January 11, 2021 and provided input on the proposed measure. The MAP offered conditional support of the SNF HAI measure for rulemaking contingent upon NQF endorsement, noting that the measure adds value to the SNF QRP by presenting one overall measurement of all HAIs acquired during SNF care that result in hospitalizations, information that is not currently available. The MAP recognized that the proposed measure is intended to reflect global infection control for a facility, and may encourage SNFs to access processes and perform interventions to reduce adverse events among SNF residents that are due to HAIs. The MAP Rural Health Workgroup also agreed that the SNF HAI measure is suitable for use with rural providers in the SNF QRP. The final MAP report is available at *http://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

Additionally, measure testing was conducted on the SNF HAI measure. Split-half testing revealed the proposed measure's moderate reliability. Validity testing of the measure showed good model discrimination as the HAI model can accurately predict HAI cases while controlling for differences in resident case-mix. The SNF HAI TEP also showed strong support for the face validity of the proposed measure. For measure testing details, refer to the document titled, Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program Technical Report available on the SNF QRP Measures and Technical Information page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.* This proposed measure is not currently NQF endorsed, but CMS plans to submit the measure for NQF endorsement in the future.

d. Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, measures specified under section 1899B of the Act be endorsed by the entity with a contract under section 1890(a) of the Act, currently the National Quality Forum (NQF). In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed SNF HAI measure is not NQF endorsed, so we considered whether there are other available measures that assess HAIs in SNFs. After review of the NQF's consensus-endorsed measures, we were unable to identify any NQF endorsed measures for SNFs focused on capturing several types of severe infections attributable to the SNF setting in one composite score. For example, although the measures Percent of Residents with a Urinary Tract Infection (Long-Stay) (NQF #0684), National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infections (NQF #0138), NHSN Central Line-Associated Bloodstream Infections (NQF #0139), and NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (NQF #1717) are NQF endorsed and all report on specific types of infections, they do not provide an overall HAI rate and are not specific to the SNF setting. Additionally, although the Skilled Nursing Facility 30-Day All-Cause Readmission measure (NQF #2510), the Potentially Preventable 30-Day Post-Discharge Readmission measure for SNF QRP, and the Skilled Nursing Facility 30-Day Potentially Preventable Readmission after Hospital Discharge measure (SNFPPR) are all specific to the SNF setting, they are not solely focused on infections. We intend to submit this proposed measure to the NQF for consideration of endorsement when feasible.

Therefore, after consideration of other available measures, we find that the exception under section 1899B(e)(2)(B) of the Act applies and are proposing the measure, Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAI) Requiring Hospitalization measure beginning with the FY 2023 SNF QRP.

e. Quality Measure Calculation

The proposed measure estimates the risk-standardized rate of HAIs that are acquired during SNF care and result in hospitalization using 1 year of Medicare FFS claims data.

Both the proposed measure numerator and denominator are risk-adjusted. The measure's adjusted numerator is the estimated number of SNF stays predicted to have an HAI that results in hospitalization. The estimate starts with the observed count of the measure outcome, which is then risk-adjusted for resident characteristics and a statistical estimate of the SNF effect beyond resident case mix. The term ''SNF effect'' represents provider-specific behaviors that result in facilities' HAI rates. These behaviors may include adherence to evidence-based infection control policies and procedures. The adjusted denominator is the expected number of SNF stays with the measure outcome. The adjusted denominator is calculated by risk-adjusting the total eligible SNF stays for resident characteristics excluding the SNF effect.

The proposed measure is calculated using a standardized risk ratio (SRR) in which the predicted number of HAIs for SNF stays per provider is divided by the expected number of HAIs. For each SNF, a risk-adjusted rate of HAIs that are acquired during SNF care and result in hospitalization is calculated by multiplying the SRR by the overall national observed rate of HAIs for all SNF stays. The measure is risk-adjusted for age and gender characteristics, original reason for Medicare Entitlement, principal diagnosis during the prior proximal inpatient (IP) stay, types of surgery or procedure from the prior proximal IP stay, length of stay and ICU/CCU utilization from the prior proximal IP stay, dialysis treatment from the prior proximal IP stay, and HCC comorbidities and number of prior IP stays within 1 year preceding the SNF stay. For technical information about this proposed measure, including information about the measure calculation, risk adjustment, and exclusions, refer to the document titled, Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program Technical Report available on the SNF QRP Measures and Technical Information page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.* If this measure is finalized, we intend to publicly report this measure using four quarters of claims data. We refer readers to section VII.H.2. of this proposed rule for information regarding public reporting.

[35] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 12, 2021.

We invited public comment on our proposal to adopt the quality measure, the Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalization measure (SNF HAI measure), beginning with the FY 2023 SNF QRP.

The following is a summary of the public comments received on our proposal to adopt the quality measure, Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalization measure (SNF HAI measure), beginning with the FY 2023 SNF QRP and our responses:

Comment: Several commenters supported adoption of the SNF HAI measure beginning with the FY 2023 SNF QRP. The Medicare Payment Advisory Commission (MedPAC) supported the adoption of the measure, stating that Medicare quality programs should include population-based outcome measures and the rate of infections acquired during a SNF stay that are severe enough to require hospitalization is an outcome of importance to beneficiaries and the Medicare program. Additionally, commenters noted that HAIs are potentially preventable and signal actionable gaps in care quality. Commenters agree that the measure is actionable in reducing HAI incidence, and does not add burden to providers through its use of Medicare FFS claims. One commenter supported interoperability of the measure in its future expansion to other post-acute care settings, such as IRFs and LTCHs. Another commenter supported the SNF HAI measure, recognizing emerging evidence that associates high SNF HAI rates with higher patient COVID–19 spread. Additional commenters supported the overall concept of the SNF HAI measure, recognizing the effectiveness of the measure to prevent and control the spread of infections and improve transparency among providers.

Response: We thank commenters for their support of the SNF HAI measure. We agree that there is a critical need to reduce HAIs in SNFs and that monitoring SNF HAI rates provides valuable information on a SNF's quality of care. We believe this proposed quality measure will address the lack of HAI data in SNFs, increase transparency, and help reduce rates of HAIs.

Comment: One commenter disagreed with the assertion that there is a performance gap regarding HAIs in SNFs. The commenter noted that there is an inability to define the magnitude of the issue which makes it difficult to identify benchmarks and goals.

Response: Our analysis of FY 2019 data demonstrated that there is a performance gap in HAI rates across SNFs. Among the 14,102 SNFs included in the sample for the analysis, risk-adjusted measure scores ranged from a minimum of 2.36 percent to a maximum of 17.62 percent.[36] Further, a 2014 report from the Office of the Inspector General (OIG) estimated that one in four adverse events among SNF residents are due to HAIs.[37] Although most HAIs are not considered ''never-events,'' most are preventable and result from inadequate care processes and structures.[38] Including the SNF HAI measure in the SNF QRP would provide SNFs information to help them improve their infection control and prevention strategies, as they will learn about their own facility's HAI rate compared to their peer SNFs and the national average. Including the SNF HAI measure in the SNF QRP would also help patients choose which SNF they would like to receive care from.

Comment: A commenter supported the SNF HAI measure's focus on infection prevention in the nursing facility, but was concerned that FY 2019 data would be used as a benchmark for HAI performance and that FY 2019 data do not take into account changes in infection prevention requirements like those at 42 CFR 483.80(b), which requires the facility to designate one or more individual(s) as the infection preventionist(s) responsible for the facility's infection prevention and control program.

Response: We would like to clarify that FY 2019 data are not being used as a benchmark for HAI performance. This measure compares facilities' HAI rates to their peers (that is, all other SNFs in the United States), and to the national average. Therefore, the benchmark of this measure's performance is the national average of the reporting period, not specifically FY 2019. With regard to the infection preventionist role, we note that under § 483.80, facilities have been required to establish an infection prevention and control program since late 2016 prior to the infection preventionist role requirement effective late 2019.

Comment: Several commenters recommended that CMS postpone implementation of the measure until it receives NQF endorsement. These comments advocated for use of NQF-endorsed measures, indicating that the NQF process includes a robust measure review with routine measure maintenance to reflect changes in performance.

Response: We direct readers to section VII.C.1.d. of this final rule, where we discuss this topic in detail. Despite the current absence of NQF endorsement, we still believe it is critical to adopt the SNF HAI measure into the FY 2023 SNF QRP as one in four adverse events among SNF residents are due to HAIs, and approximately more than half of all HAIs are potentially preventable.[39] Identifying several types of severe HAIs attributable to the SNF setting in one composite score provides actionable information to providers that may hold them accountable, encourage them to improve the quality of care they deliver, and improve transparency. Although the SNF HAI measure is not currently endorsed by the NQF, we agree that there is value in obtaining measure endorsement and plan to submit the measure for NQF endorsement in the future.

Comment: Several commenters opposed the use of Medicare FFS claims for the SNF HAI measure. Many commenters do not believe that claims-based measures are appropriate for measuring HAIs, and would instead support the use of NHSN chart-abstracted surveillance data. Commenters emphasized the scientific process that ensures integrity and accuracy of NHSN data while questioning the reliability of claims data. Another commenter suggested using NHSN data in conjunction with claims data, noting the benefits of using standardized, validated NHSN definitions.

Response: As mentioned in the SNF HAI Final TEP Summary Report, some TEP members voiced concerns about the accuracy of using inpatient claims to accurately capture infections acquired in a SNF.[40] The TEP discussed

[36] Acumen LLC & CMS. (2021). Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program: Technical Report. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

[37] Office of Inspector General. (2014). Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries. Retrieved from *https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.*

[38] CMS. (2006). Eliminating Serious, Preventable, and Costly Medical Errors—Never Events. Retrieved from *https://www.cms.gov/newsroom/fact-sheets/eliminating-serious-preventable-and-costly-medical-errors-never-events.*

[39] Office of Inspector General. (2014). Adverse events in skilled nursing facilities: National incidence among Medicare beneficiaries. Retrieved from *https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.*

[40] Levitt, A.T., Freeman, C., Schwartz, C.R., McMullen, T., Felder, S., Harper, R., Van, C.D., Li, Q., Chong, N., Hughes, K., Daras, L.C., Ingber, M.,

alternative data sources, including the use of NHSN data, but ultimately decided against it as it would increase provider burden. The TEP ultimately agreed that claims data are high quality and would strengthen the SNF QRP measure portfolio without increasing provider burden. Additionally, other claims-based measures have been deemed reliable through NQF endorsement, such as the Skilled Nursing Facility 30-Day All-Cause Readmission measure (SNFRM) (NQF #2510).

Comment: Many commenters opposed the use of Medicare claims due to concerns that its data delay would not allow for timely improvement of the HAI rate.

Response: We have worked to streamline our public reporting processes, and to narrow the gap between the submission of claims data and the public display of that data. To ensure that we give ample time for providers to submit their claims data, we have established a 90-day run-out period following the end of a calendar year or fiscal year. Beyond that, there are specific administrative and review/quality assurance processes that must take place in a sequential order for CMS to ensure we are displaying accurate data. We have narrowed this gap between claims submission and public display to the extent feasible at this time.

Comment: Commenters expressed concern over the measure's dependence on the diagnosis of patients by medical practitioners who are outside of the influence of the SNF. These commenters are concerned that because the measure outcome is calculated based on hospital information, not SNF information, it reflects the coding practices of hospitals rather than actual quality of care at SNFs. Commenters also expressed concerns about differences in hospital surveillance that may result in an inaccurate SNF HAI rate.

Response: We use inpatient claims for the SNF HAI measure because the measure's main outcome is HAIs that require hospitalization. In response to the commenters' assertion that inpatient claims are unreliable, a medical record review on the accuracy of hospital coding of Hospital Acquired Conditions (HACs) and Present on Admission (POA) conditions did not find patterns of widespread underreporting of HACs or overreporting of POA status.[41] Rather, the study found that only 3 percent of HAC cases were underreported and 91 percent of all cases coded POA were coded accurately. Another medical record review conducted by us assessed the accuracy of the principal diagnosis coded on a Medicare claim to identify whether a patient was admitted for a diagnosis included in our list of potentially preventable readmission (PPR) diagnoses.[42] The study analyzed inpatient discharges from October 2015 through September 2017 and found high agreement between principal diagnoses in Medicare claims and corresponding medical records. Specifically, the agreement rate between principal diagnoses in Medicare claims and information in the corresponding medical records ranged from 83 percent to 94 percent by study hospital. Additionally, 91 percent to 97 percent of principal diagnoses from the corresponding medical records were included in CMS' list of PPR diagnoses. Therefore, we disagree with commenters' concerns about the accuracy of inpatient claims data.

In addition, several other SNF QRP measures rely on data from other settings such as Skilled Nursing Facility 30-Day Potentially Preventable Readmission after Hospital Discharge (SNFPPR), Skilled Nursing Facility 30-Day All-Cause Readmission (SNFRM) (NQF #2510), and Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting.

Comment: Several commenters disagreed with the measure's restriction to only include HAIs that require inpatient hospitalization and to exclude emergency room visits and observation stays. These commenters believe that limiting HAIs to only those that require hospitalization will undercount preventable HAIs and lead to negative outcomes for residents.

Response: We acknowledge that detecting all HAIs in the measure's definition would increase the amount of infection data provided to SNFs and empower quality improvement. However, we decided to propose only including HAIs requiring hospitalization in our measure definition in response to suggestions by the TEP.[43] One TEP member noted that SNFs could risk information overload if we include every possible HAI in the SNF HAI rate.

TEP members ultimately recommended that it would be more valuable for SNFs to have a concentrated list of severe infections to target quality improvement in the biggest impact areas. Avoiding information overload will help to make the measure more actionable, as SNFs may be able to target the focus of their infection and prevention control programs on their residents' most severe infections. The TEP also recommended excluding observation stays and emergency department visits out of concern that these stays are not long enough to acquire all the lab results needed for accurate diagnosis of infections.

Overall, TEP members believed that diagnoses of SNF residents transferred and hospitalized would be more likely to be based on the whole history and comprehensive test results and thus more likely to represent true infections.

Comment: Some commenters opposed the adoption of a composite score, with concern that the measure is not infection-specific and would not allow for timely facility-level targeted interventions. One commenter recommended to narrow the SNF HAI measure to specific infections such as central line-associated bloodstream infections (CLASBI) or catheter-associated urinary tract infections (CAUTI). This commenter noted that focusing on a couple of infections could make it easier to isolate performance issues and focus on improving those outcomes.

Response: The SNF HAI composite score is intended to provide a summary of overall performance in HAI prevention and control. Rather than focusing on interventions targeting a single infection, the goal of this measure is for SNFs to focus on foundational safety interventions, such as rates of hand washing, vaccinations, and

Smith, L., & Erim, D. (2019). Final Technical Expert Panel Summary Report: Development of a Healthcare-Associated Infections Quality Measure for the Skilled Nursing Facility Quality Reporting Program. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNF-HAI-Final-TEP-Report-7-15-19_508C.pdf.*

[41] Cafardi, S.G., Snow, C.L., Holtzman, L., Waters, H., McCall, N.T., Halpern, M., Newman, L., Langer, J., Eng, T., & Guzman, C.R. (2012). Accuracy of Coding in the Hospital-Acquired Conditions-Present on Admission Program Final Report. Retrieved from *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitalacqcond/downloads/accuracy-of-coding-final-report.pdf.*

[42] He, F., Daras, L.C., Renaud, J., Ingber, M., Evans, R., & Levitt, A. (2019, June 3). Reviewing Medical Records to Assess the Reliability of Using Diagnosis Codes in Medicare Claims to Identify Potentially Preventable Readmissions. Retrieved from *https://academyhealth.confex.com/academyhealth/2019arm/meetingapp.cgi/Paper/31496.*

[43] Levitt, A.T., Freeman, C., Schwartz, C.R., McMullen, T., Felder, S., Harper, R., Van, C.D., Li, Q., Chong, N., Hughes, K., Daras, L.C., Ingber, M., Smith, L., & Erim, D. (2019). Final Technical Expert Panel Summary Report: Development of a Healthcare-Associated Infections Quality Measure for the Skilled Nursing Facility Quality Reporting Program. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNF-HAI-Final-TEP-Report-7-15-19_508C.pdf.*

antibiotic stewardship programs that will reduce all instances of infection. We believe that reporting a composite, facility-level score is valuable because it informs SNFs of their overall HAI rates and allows them to compare these rates to their peers. This will enable SNFs to track their own performance and improve their quality of care through infection prevention and control programs. However, we recognize the benefits of measuring infection-specific data and will consider developing infection-specific HAI measures in the future.

Comment: One commenter urged that the SNF HAI measure should include mitigation approaches to prevent misattribution of a HAI to a SNF. This commenter also recommended that the measure implement infection-specific incubation periods and states that the COVID–19 pandemic has exposed the importance of infection-specific incubation periods. COVID–19 infections can occur before the onset of symptoms or a positive infection test result is observed, and in many cases, residents may have been exposed to COVID–19 prior to SNF admission.

Response: We acknowledge the difficulties of assigning attribution in the SNF setting since HAIs often have risk factors that are outside of the SNF's control. Although most are preventable, HAIs are not considered to be ''never-events'' and we acknowledge that residents may contract infections outside of the SNF. However, we note that it is the responsibility of the SNF to implement infection prevention protocols and to best manage infections when they occur. Further, to help prevention misattribution, the measure excludes certain community-acquired infections, implements an incubation window, and applies the Centers for Disease Control (CDC) and Prevention's National Healthcare Safety Network (NHSN) Repeat Infection Timeframe (RIT) to exclude preexisting infections that were acquired from the prior inpatient stay. Predating the COVID–19 pandemic, we obtained clinical input from TEP panelists on the SNF HAI measure about the time window to identify HAIs attributable to the SNF.[44] The TEP agreed that the same time window should be applied to all infections. Although the selected incubation window may not hold true for all infections, TEP members noted it was a reasonable average.

Since COVID–19 was not discussed during TEP proceedings, we will consider working with the CDC to determine whether or not this reasonable average approach is still appropriate or if we should consider establishing an infection-specific incubation window to account for COVID–19 in the future.

Comment: Several commenters did not find the measure actionable, citing that they would only have access to facility-level data rather than patient-level information. Commenters requested patient-level data in confidential feedback reports be available through the Certification and Survey Provider Enhanced Reports (CASPER) system, noting its importance in improving provider transparency and actionability. Additionally, commenters expressed the importance of providing facilities with infection-specific data to help reduce future infection prevalence.

Response: We disagree with the commenters that the use of facility-level data for the measure makes it less actionable. One of the benefits of a facility-level, composite indicator is its simplicity. A single score, representative of an entire facility, is easier to interpret, easier to use as a benchmark for tracking performance, and easier to use for comparisons among peers. The measure is not intended to stand alone; rather, it can be used in conjunction with other surveillance activities to plan for quality improvement. While an overall facility HAI rate may not provide information for targeting HAI prevention efforts to specific infection types, we believe that aggregate HAI prevalence data still provides actionable feedback to SNFs. The prevention of HAIs is not specific to an individual type of infection that can be presented in patient-level feedback reports. Rather, infection prevention and control efforts should address multiple infection types and SNFs should already be implementing infection control practices that include various approaches such as vaccination, isolation, hand washing, antibiotic stewardship programs, surveillance, sanitation, and staff training. Therefore, a facility-level HAI score is a reflection of quality of care as it measures a SNF's adeptness in infection prevention and management.

Comment: We received several comments about risk adjustment of the SNF HAI measure. One commenter disagreed that the SNF HAI measure should be risk-adjusted, especially for factors that are under facility control. This commenter believes that risk adjustment masks poor outcomes for residents that result directly from poor quality of care because risk adjustment excuses facilities from properly caring for high-risk patients.

Response: We share the commenters' concern that inclusion of certain covariates could mask adverse outcomes. However, lack of risk adjustment would disadvantage SNFs that specialize in treating high-risk populations in terms of HAI performance. In order to prevent provider manipulation, we focused on selecting factors that are not under the control of SNFs, such as patient characteristics rather than service provision. We would like to emphasize that the goal of this risk-adjusted measure is to identify SNFs that have *notably higher rates* of HAIs acquired during SNF care, when compared to the national average HAI rate. The purpose of risk adjustment is to account for risk factor differences across SNFs, when comparing quality of care among them. In other words, risk adjustment ''levels the playing field'' and allows for fairer quality-of-care comparisons across SNFs by controlling for differences in resident case-mix. Risk adjustment is particularly important for outcome measures because resident outcomes may be affected by factors such as age, gender, and health status that go beyond the quality of care delivered by SNFs.

Comment: A few commenters supported risk adjustment but considered the proposed risk adjustment approach as inadequate and missing patient-level and provider-level factors. One commenter specifically asked that the measure be risk adjusted to account for high rates of patients with spinal cord injuries.

Response: The risk adjustment model accounts for several patient-level factors such as age, sex, original reason for Medicare Entitlement, 283 principal diagnoses Clinical Classification Software (CCS) categories, 79 Hierarchical Condition Categories (HCC) comorbidities, 10 surgical procedure CCS categories from the prior proximal stay, length of stay, and intensive care unit (ICU)/critical care unit (CCU) utilization from the prior proximal stay. We would like to clarify that spinal cord injuries are included in the risk adjustment model as CCS 227 *spinal cord injury* and HCC72 *spinal cord disorders/injuries.*

Comment: One commenter was concerned about the lack of adjustment for social risk factors.

Response: Risk adjustment includes age and sex but we acknowledge that

[44] Levitt, A.T., Freeman, C., Schwartz, C.R., McMullen, T., Felder, S., Harper, R., Van, C.D., Li, Q., Chong, N., Hughes, K., Daras, L.C., Ingber, M., Smith, L., & Erim, D. (2019). Final Technical Expert Panel Summary Report: Development of a Healthcare-Associated Infections Quality Measure for the Skilled Nursing Facility Quality Reporting Program. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNF-HAI-Final-TEP-Report-7-15-19_508C.pdf.*

the measure does not address social risk factors, such as income nor race/ethnicity. During the development of the SNF HAI measure, the NQF was conducting a Social Risk Trial to investigate social risk factors' association with outcome measures. Past NQF guidelines stated that social risk factors should not be included as adjustment variables. After the 2021 conclusion of the trial, the NQF acknowledged that adjusting for social risk factors can obscure disparities and the Disparities Standing Committee recommended that each performance measure be assessed individually to determine appropriateness of adjustment for social risk factors.[45] It is unclear if the benefits of adjusting for other social risk factors in the SNF HAI measure outweigh the potential consequences of masking social disparities. Therefore, we proposed to exclude social risk factors for now, but will continue to evaluate this issue by monitoring disparities and social risk factors as part of our routine measure monitoring work.

Comment: One commenter believes that risk adjustment is inappropriately applied at the patient level and hospital level due to the use of inpatient claims, rather than at the SNF level.

Response: SNF HAI risk adjustment is not implemented at the patient level nor at the hospital level. While the measure uses inpatient claims to identify HAIs acquired during a SNF stay, the unit of analysis for the risk adjustment is at the SNF stay level. The risk adjustment model applies a SNF provider-specific intercept via a hierarchical modeling approach. For more information about our risk adjustment approach, we refer to the SNF HAI Technical Report.[46]

Comment: One commenter advocated for CMS to be transparent about the measure's calculations, noting that providers should be able to calculate their own HAI rate for measure validation, if necessary.

Response: While we intend to make as much information related to SNF HAI performance as possible available to SNFs through confidential feedback reports under section 1899B(f) of the Act, we understand that claims-based quality measurement is difficult for SNFs to replicate for validation purposes. It would require familiarity with a number of data sources that are used to develop the risk-adjustment model for SNF HAI in order to account for variation across SNFs in case-mix and patient characteristics predictive of HAIs requiring hospitalization (including the Medicare Enrollment Database [EDB], Agency for Healthcare Research & Quality [AHRQ] Clinical Classification Software [CCS] groupings of ICD–10 codes, and CMS's HCC mappings of ICD–10 codes). We view this as a necessary compromise to minimize reporting burden on participating SNFs by using claims data while ensuring we obtain timely data for quality improvement. We refer readers to the SNF HAI Technical Report for more information regarding the measure's specifications and formulas used for rate calculations.[47]

Comment: One commenter did not support the measure because its testing results demonstrated moderate reliability.

Response: We used FY 2018 and 2019 data to conduct split-half reliability analyses to assess the internal consistency of the measure. Although our results showed moderate measure reliability, the MAP offered conditional support of the measure contingent upon NQF endorsement based on the above reliability results as well as other testing results.[48] Additional measure testing results revealed high reportability and usability, high variability, strong face validity, and good model discrimination.[43] We plan to submit the measure for NQF endorsement in the future.

Comment: Some commenters highlighted their concerns regarding SNF HAI and COVID–19, noting the challenges they faced during the PHE, and how these challenges may impact their SNF HAI measure rates.

Response: We acknowledge the severity of the pandemic and its detrimental impact on SNFs. As included in section VII.H.3. of this final rule, we proposed that no data reflecting services provided in FY 2020 would be publicly reported, as this measure would only be publicly reported using FY 2019 and FY 2021 data. We recognize that quality data collection and reporting for services furnished during the PHE may not be reflective of their true level of performance during this time of emergency. At the same time, COVID–19 has heightened the importance of infection prevention and control programs and the need for HAI data.

Comment: One commenter linked the SNF HAI measure to health equity through the use of Medicare claims, noting that the measure should report demographic information such as race and ethnicity to shed light on potential health care disparities among SNF residents.

Response: We plan to track sex, age, race, ethnicity, and Medicare/Medicaid dual-eligibility status as part of CMS' routine monitoring and evaluation of the SNF HAI measure. This information will not be displayed on Care Compare as part of SNF HAI measure reporting, but we will take this request into consideration in our future efforts to promote health equity.

Comment: Some commenters urged CMS to provide resources, support, and trainings for quality improvement and infection prevention among SNFs. Commenters encourage CMS to work with stakeholders to consider the labor required to measure and prevent HAIs in SNFs under the critical shortage of healthcare personnel, and recommend for CMS to implement a requirement for SNFs to hire at least one person trained in infection control to be available at the facility, with their hours predicated on the number of beds.

Response: We would like to emphasize that SNFs should already be maintaining infection control programs in order to meet the quality requirements for certification in the Medicare program as outlined in the long-term care facility Requirements of Participation (RoPs). These regulations at § 483.80 require facilities to establish and maintain an infection prevention and control program, including designating one or more individual(s) as the infection preventionist who works at least part time at the facility and who is responsible for the facility's infection prevention and control program.

Comment: Other commenters urge CMS to train SNFs on best practices for reducing HAIs.

Response: We have made several resources available such as free online

[45] National Quality Forum (NQF). (2021). Social Risk Trial Final Report: Draft Report—Version 2. Retrieved from *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95208.*

[46] Acumen LLC & CMS. (2021). Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program: Technical Report. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

[47] Acumen LLC & CMS. (2021). Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program: Technical Report. Retrieved from *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

[48] National Quality Forum (NQF). (2021). Measure Applications Partnership 2020–2021 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC. Retrieved from *http://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

training modules in partnership with the CDC and Quality Improvement Organizations (QIOs). The QIO program aims to increase patient safety and care coordination, and improve clinical quality by, among other things, working with providers, other stakeholders, and Medicare beneficiaries on initiatives to improve the quality of health care for Medicare beneficiaries. Several of these resources can be found on the following web pages as provided by the CDC: *https://www.cdc.gov/longtermcare/prevention/index.html* and *https://www.cdc.gov/longtermcare/training.html.* Additionally, the CMS Office of Minority Health (OMH) offers a Disparity Impact Statement as an intervention to address HAI-related disparities. This tool may be used to provide health equity technical assistance and reduce HAIs among vulnerable populations. The Disparity Impact Statement tool can be viewed at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.*

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the SNF HAI measure as a Medicare FFS claims-based measure beginning with the FY 2023 payment determination and subsequent years as proposed.

2. COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2023 SNF QRP

a. Background

On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS-CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[49] COVID–19 is a contagious respiratory infection [50] that can cause serious illness and death. Older individuals, racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[51] [52] As stated in the proposed rule, as of April 4, 2021, the U.S. reported over 30 million cases of COVID–19 and over 553,000 COVID–19 deaths.[53] As of July 21, 2021, the U.S. has reported over 34 million cases of COVID–19 and over 607,000 COVID–19 deaths.[54]

Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[55] In December 2020 and January 2021, media outlets reported that more than 100,000 Americans were in the hospital with COVID–19.[56]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[57] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[58] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface.[59] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS-CoV–2 infection, regardless of whether the individual has symptoms.[60] Subsequent to the publication of the proposed rule, the CDC has confirmed that the three main ways that COVID–19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.[61] Personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, but COVID–19 can still spread between healthcare personnel (HCP) and patients given the close contact that may occur during the provision of care.[62] The CDC has emphasized that health care settings, including long-term care settings, can be high-risk places for COVID–19 exposure and transmission.[63]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[64] On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[65] Subsequently the FDA issued EUAs for additional COVID–19 vaccines. In issuing these EUAs, the FDA determined that it was reasonable to conclude that the known and potential benefits of each vaccine, when used as

[49] U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Retrieved from *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[50] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Retrieved from *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[51] Centers for Disease Control and Prevention (2021). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[52] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[53] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[54] Ibid.

[55] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895.* Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.*

[56] NPR. U.S. Hits 100,000 COVID–19 Hospitalizations, Breaks Daily Death Record. Dec. 2, 2020. Accessed on December 17, 2020 at *https://www.npr.org/sections/coronavirus-live-updates/2020/12/02/941902471/u-s-hits-100-000-covid-19-hospitalizations-breaks-daily-death-record;* The Wall Street Journal. Coronavirus Live Updates: U.S. Hospitalizations, Newly Reported Cases, Deaths Edge Downward. Accessed on January 11 at *https://www.wsj.com/livecoverage/covid-2021-01-11.*

[57] Centers for Disease Control and Prevention. (2021). COVID–19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[58] Centers for Disease Control and Prevention (2021). COVID–19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[59] Centers for Disease Control and Prevention (2021). COVID–19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[60] Centers for Disease Control and Prevention. (2020). Clinical Questions about COVID–19: Questions and Answers. Accessed on December 2, 2020 at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html.*

[61] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on July 15, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[62] Centers for Disease Control and Prevention. (2020). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on December 2 at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html.*

[63] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[64] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[65] U.S. Food and Drug Administration. (2021). Pfizer-BioNTech COVID–19 Vaccine. Available at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.* U.S. Food and Drug Administration. (2021). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/150386/download.*

authorized to prevent COVID–19, outweighed its known and potential risks.[66 67 68]

As part of its national strategy to address COVID–19, the Biden administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[69] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including healthcare personnel (HCP), and individuals at highest risk for developing severe illness from COVID–19.[70] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity.[71] Research suggests most states followed this recommendation,[72] and HCP began receiving the vaccine in mid-December of 2020.[73] Subsequent to the publication of the SNF PPS proposed rule, on April 8, 2021, the White House confirmed that there was sufficient vaccine supply for all Americans.[74]

HCP are at risk of carrying COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, and the general public. We believe it is important to require that SNFs report HCP vaccination in order to assess whether they are taking steps to limit the spread of COVID–19 among their HCP, reduce the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of SNFs to continue serving their communities throughout the PHE and beyond. Currently, as required under the May 8, 2020 interim final rule with comment period (85 FR 27601–27602), SNFs are required to submit COVID–19 data through the CDC's NHSN Long-term Care Facility COVID–19 Module of the NHSN. Examples of data reported in the module include: Suspected and confirmed COVID–19 infections among residents and staff, including residents previously treated for COVID–19; total deaths and COVID–19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies available in the facility; resident beds and census; access to COVID–19 testing while the resident is in the facility; and staffing shortages. Although HCP and resident COVID–19 vaccination data reporting modules are currently available through the NHSN, the reporting of this data is voluntary.[75] Subsequent to the publication of the SNF PPS proposed rule, an interim final rule with comment period (IRC) published on May 13, 2021 entitled ''Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff'' (86 FR 26315–26316) (hereafter referred to as the May 2021 IFC), SNFs are required to report to the CDC's NHSN, on a weekly basis, the COVID–19 vaccination status of all residents and staff.

We also believe that publishing facility-level COVID–19 HCP vaccination rates on Care Compare would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID–19 Vaccination Coverage among Healthcare Personnel measure addresses the quality priority of ''Promote Effective Prevention & Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

Therefore, we proposed a new measure, COVID–19 Vaccination Coverage among HCP to assess the proportion of a SNF's healthcare workforce that has been vaccinated against COVID–19.

b. Stakeholder Input

In the development and specification of the measure, a transparent process was employed to seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, under section 1890A of the Act.[76] To meet this requirement, the following opportunity was provided for stakeholder input.

The pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures Under Consideration (MUC) List that the Secretary is considering adopting, through Federal rulemaking process, for use in Medicare program(s). This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list. The COVID–19 Vaccination Coverage among HCP measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List).[77] Five comments were received from industry stakeholders during the pre-rulemaking process on the COVID–19 Vaccination Coverage among HCP measure, and support was mixed. Commenters generally supported the concept of the measure. However, there was concern about the availability of the vaccine and

[66] Ibid.

[67] U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download.*

[68] U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.*

[69] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. March 29, 2021. Accessed at *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/.*

[70] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf;* Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[71] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[72] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.*

[73] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.*

[74] Press Briefing by White House COVID–19 Response Team and Public Health Officials | The White House.

[75] Centers for Disease Control and Prevention. Weekly COVID–19 Vaccination Data Reporting. Accessed at *https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html.*

[76] Centers for Medicare & Medicaid Services. Pre-rulemaking. Accessed at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking.*

[77] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 12, 2021.

measure definition for HCP, and some commenters encouraged CMS to continue to update the measure as new evidence comes in.

c. Measure Applications Partnership (MAP) Review

When the Measure Applications Partnership (MAP) PAC–LTC Workgroup convened on January 11, 2021, it reviewed the MUC List and the COVID–19 Vaccination Coverage among HCP measure. The MAP recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the SNF QRP measure set by providing transparency about an important COVID–19 intervention to help limit COVID–19 infections.[78] The MAP also stated that collecting information on COVID–19 vaccination coverage among healthcare personnel and providing feedback to facilities would allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing rates of COVID–19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness.[79]

In its preliminary recommendations, the MAP PAC–LTC Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[80] To mitigate its concerns, the MAP believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[81] Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 Vaccination Coverage among Healthcare Personnel measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measure back to the MAP once the specifications are further clarified. The final MAP report is available at *http://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

In response to the MAP request for CMS to bring the measure back once the specifications were further clarified, CMS met with the MAP Coordinating Committee on March 15, 2021. First, CMS and CDC clarified the alignment of the COVID–19 Vaccination Coverage among HCP with the Influenza Vaccination Coverage among HCP (NQF #0431), an NQF-endorsed measure since 2012. The COVID–19 Vaccination Coverage among HCP measure is calculated using the same approach as the Influenza Vaccination Coverage among HCP measure.[82] The approach to identifying HCPs eligible for the COVID–19 vaccination is analogous to those used in the NQF endorsed flu measure which underwent rigorous review from technical experts about the validity of that approach and for which ultimately received NQF endorsement. More recently, prospective cohorts of health care personnel, first responders, and other essential and frontline workers over 13 weeks in eight U.S. locations confirmed that authorized COVID–19 vaccines are highly effective in real-world conditions. Vaccine effectiveness of full immunization with two doses of vaccines was 90 percent.[83]

Additionally, to support the measure's data element validity, CDC conducted testing of the COVID–19 vaccination numerator using data collected through the NHSN and independently reported through the Federal Pharmacy Partnership for Long-term Care Program for delivering vaccines to long-term care facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination, the number of HCP vaccinated in approximately 1,200 facilities which had data from both systems, the number of HCP vaccinated was highly correlated between these two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting. Of note, assessment of data element reliability may not be required by NQF if data element validity is demonstrated.[84] To assess the validity of new performance measure score (in this case, percentage of COVID–19 vaccination coverage), NQF allows assessment by face validity (that is, subjective determination by experts that the measure appears to reflect quality of care, done through a systematic and transparent process),[85] and the MAP concurred with the face validity of the COVID–19 Vaccination Coverage among HCP measure. Materials from the March 15, 2021 MAP Coordinating Committee meeting are on the NQF website at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

This measure is not NQF endorsed, but the CDC, in collaboration with CMS, plans to submit the measure for NQF endorsement in the future.

d. Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that absent an exception under section 1899B(e)(2)(B) of the Act, each measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, currently the National Quality Forum (NQF). In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The proposed COVID–19 Vaccination Coverage among HCP measure is not currently NQF endorsed and has not been submitted to the NQF for consideration, so we considered whether there are other available measures that assess COVID–19 vaccinations among HCP. After review of the NQF's consensus-endorsed measures, we were unable to identify any NQF endorsed measures for SNFs focused on capturing COVID–19 vaccination coverage of HCP, and we found no other feasible and practical measure on the topic of COVID–19 vaccination coverage among HCP. The only other vaccination coverage of HCP measure found was the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which is NQF endorsed and was adopted in the IRF QRP in the FY 2014 IRF PPS final rule (78 FR 47905 through 47906), and in the LTCH QRP in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631).

[78] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on February 3, 2021 at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.*

[79] Ibid.

[80] Ibid.

[81] Ibid.

[82] The Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which is NQF endorsed and was adopted in the IRF QRP in the FY 2014 IRF PPS Final Rule (78 FR 47905 through 47906), and in the LTCH QRP in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53630 through 53631).

[83] Centers for Disease Control and Preventions. Morbidity and Mortality Weekly Report. March 29, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm?s_cid=mm7013e3_w.*

[84] National Quality Forum. Key Points for Evaluating Scientific Acceptability. Revised January 3, 2020. *https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Docs/Evaluation_Guidance.aspx#:~:text=NQF%20is%20not%20prescriptive%20about,reliability%20or%20validity%20testing%20results.&text=Reliability%20and%20validity%20must%20be,source%20and%20level%20of%20analysis*).

[85] Ibid.

Given the novel nature of the SARS–CoV–2 virus, and the significant and immediate risk it poses in SNFs, we believe it was necessary to propose the measure as soon as possible. Therefore, after consideration of other available measures that assess COVID–19 vaccination rates among HCP, we believe the exception under section 1899B(e)(2)(B) of the Act applies. This proposed measure has the potential to generate actionable data on vaccination rates that can be used to target quality improvement among SNF providers.

e. Quality Measure Calculation

The COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in facilities such as SNFs. Since this proposed measure is a process measure, rather than an outcome measure, it does not require risk-adjustment.

The denominator would be the number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[86] While the SNF QRP applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals, we believe it is necessary to include all HCP within the facility in the measure denominator because all HCP would have access to and may interact with SNF residents.

The numerator would be the cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who received a complete vaccination course against SARS–CoV–2. A complete vaccination course may require one or more doses depending on the specific vaccine used. The finalized measure specifications are on the CDC website at *https://www.cdc.gov/nhsn/nqf/index.html.*

We proposed that SNFs would submit data for the measure through the CDC/NHSN data collection and submission framework.[87] SNFs would use the COVID–19 vaccination data reporting module in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible who have worked at the facility that week (denominator) and the number of those HCP who have received a completed COVID–19 vaccination course (numerator). SNFs would submit COVID–19 vaccination data for at least 1 week each month. If SNFs submit more than 1 week of data in a month, the most recent week's data would be used for measure calculation purposes. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the 3 monthly modules of data reported for the quarter. This quarterly rate would be publicly reported on the Care Compare website. Subsequent to the first refresh, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four full quarters of data is reached. Thereafter, the measure would be reported using four rolling quarters of data on Care Compare.

For purposes of submitting data to CMS for the FY 2023 SNF QRP, SNFs would be required to submit data for the period October 1, 2021 through December 31, 2021. Following the initial data submission quarter for the FY 2023 SNF QRP, subsequent compliance for the SNF QRP would be based on four quarters of such data submission. For more information on the measure's proposed public reporting period, we refer readers to section VII.H.3. of this final rule.

We invited public comment on our proposal to add a new measure, COVID–19 Vaccination Coverage among Healthcare Personnel (HCP), to the SNF QRP beginning with the FY 2023 SNF QRP.

The following is a summary of the public comments received on our proposal to add a new measure, COVID–19 Vaccination Coverage among Healthcare Personnel (HCP), to the SNF QRP beginning with the FY 2023 SNF QRP and our responses:

Comment: A number of organizations, including provider associations and patient advocacy groups, support the proposal to adopt the COVID–19 Vaccination Coverage among HCP measure for the SNF QRP. Commenters agree that the measure would help assess the degree to which SNFs are taking steps to limit the spread of COVID–19 and reduce the risk of transmission within their facilities. Commenters pointed out that public reporting of COVID–19 vaccination among HCP on Care Compare would provide consumers with important information with which to make informed decisions about the safety of a SNF. Commenters also believe the information would provide greater transparency to Federal officials and other stakeholders seeking to effectively target vaccine hesitancy, as well as provide resources related to the COVID–19 vaccines.

Response: We thank the commenters for their support and agree that the COVID–19 Vaccination among HCP measure will help assess the degree to which SNFs are taking steps to limit the spread of COVID–19 and assess the risk of transmission within their facilities. This is consistent with information published by the CDC and others, which has emphasized that healthcare settings, including SNFs, can be high-risk places for COVID–19 exposure and transmission, and notes that COVID–19 can spread among HCP and residents given the close contact that may occur during the provision of care.[88] Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[89] We also agree with commenters that public reporting of COVID–19 Vaccination Coverage among HCP on Care Compare would provide consumers with important information with which to make informed decisions about the safety of a SNF.

Comment: One commenter cautioned against using the data in a way that adversely impacts the nursing home workforce, including SNF HCP, but believes the reporting will assist CMS to provide targeted support and education to providers.

Response: The SNF QRP helps inform health care consumers about the quality of healthcare SNFs provide to their residents. The measure does not impose additional requirements on the HCP workforce. We agree with the commenter that public reporting of the COVID–19 Vaccination Coverage among HCP measure on Care Compare would provide consumers with important information with which to make informed decisions about the safety of a SNF.

Comment: Another commenter urged CMS to require provider reporting of other activities related to vaccination, such as whether paid leave is provided for HCP to take off from work and recover from any side effects

[86] Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United Sates. Contraindications found in Appendix B: Triage of people presenting for the vaccination. Accessed at *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.*

[87] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

[88] Chen MK, Chevalier JA, Long EF. Nursing home staff networks and COVID–19. Proceedings of the National Academy of Sciences of the United States of America (PNAS). Available at *https://www.pnas.org/content/118/1/e2015455118.* Accessed June 29, 2021.

[89] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Retrieved from *https://www.cdc.gov/vaccines/imzmanagers/downloads/COVID-19.*

experienced after taking the vaccine, believing this would make it easier for HCP to obtain vaccination.

Response: We appreciate the commenters' suggestions to collect additional information related to vaccinations, however CMS does not presently have the statutory authority to collect information related to paid leave or the side effects experienced after taking the vaccine.

Comment: A few commenters recommended the measure should include all personnel in the facility, such as social services, dietary, and housekeeping, not just personnel who have direct contact with residents.

Response: We proposed to include all HCP within the facility, such as social services, dietary and housekeeping, and refer readers to section VI.C.2.e. of the FY 2022 SNF proposed rule and to the Instructions for Completion of the Weekly Healthcare Personnel COVID–19 Vaccination Cumulative Summary for Long-Term Care Facilities (57.219, REV 3) at *https://www.cdc.gov/nhsn/forms/instr/57.219-toi-508.pdf* which details all HCP included in the measure.

Comment: One commenter stated the COVID–19 Vaccination Coverage among HCP is superfluous given the fact that CMS also proposed the SNF HAI measure which they believe to be a better indicator of a SNF's overall infection prevention practices.

Response: We disagree with the commenter's statement that the COVID–19 Vaccination Coverage among HCP measure is superfluous since the measure and the SNF HAI measure each assess distinct aspects of infection prevention. The COVID–19 Vaccination among HCP measure assesses the percentage of HCP in the facility who have received a complete vaccination course for SARS–CoV–2. The SNF HAI measure assesses the percentage of healthcare acquired infections that result in a hospitalization. While it is true that the SNF HAI measure may capture a subset of the COVID–19 cases that result in hospitalization, we believe both measures are distinct and necessary to assess SNFs' practices to mitigate hospitalizations for infections. Additionally, we believe it is important for patients and caregivers to have the COVID–19 Vaccination Coverage among HCP measure data to help them more directly assess how a SNF is mitigating the risk of COVID–19 transmission.

Comment: One commenter was encouraged by the CDC's measure validity testing following the MUC formal comment period earlier this year and the measure specifications subsequently delineated by the CDC in March 2021. Given the measure's potential to generate actionable data on vaccination rates, they think it is important for CMS, in collaboration with the CDC, to continue to hone the measure as it is submitted for NQF endorsement in the future.

Response: We thank the commenter for their support and we will continue to collaborate with the CDC. The CDC, in collaboration with CMS, are planning to submit the measure for consideration in the NQF Fall 2021 measure cycle.

A number of commenters wrote in support of the measure's concept and the need to encourage widespread vaccination among HCP. However, there were also several concerns with the measure, including burden, lack of access to the vaccine, concerns of staff intimidation if they elect not to receive the vaccine, the fact that it is unknown whether a booster vaccination will be necessary, and concern that the vaccinations have not received full FDA approval. We address each of these comments separately below:

Comment: A couple of commenters spoke to the fact that COVID–19 vaccination administration has been fragmented and challenging and were concerned whether vaccine supply would remain sufficient across the nation to ensure all HCP could receive it.

Response: As part of its national strategy to address COVID–19, the current administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy. The goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one. While we acknowledge that vaccine supply was initially limited, more than 20 states are no longer ordering all the vaccine doses allocated to them due to decline in demand,[90] and more than 1,000 counties are reporting a surplus of vaccine appointments.[91] We understand that vaccine availability may vary based on location, and vaccination and medical staff authorized to administer the vaccination may not be readily available in all areas. Supply distribution is the responsibility of each state, and SNFs should continue to consult state and local health departments to understand the range of options for how vaccine provision can be made available to HCP.

Comment: A couple of commenters expressed concern over the potential for inequality among SNFs because one-dose vaccines are not equally available across the nation. They stated some SNFs would be at a disadvantage because of the 4-week waiting period between doses of the two-dose vaccines to reach complete vaccination status.

Response: This measure provides information to patients about the extent to which HCP have completed a COVID–19 vaccination course during a defined period of time. Given this goal, geographic variation in vaccine availability, including the types of vaccines available, ultimately does not make the information captured by this measure any less valuable to stakeholders.

Because we proposed to begin reporting the COVID–19 Vaccination Coverage among HCP measure using one quarter of data, there will be time during each quarter for persons receiving the two-dose vaccine to reach complete vaccination status. In the event that an HCP does not complete a vaccination course during a reporting period, they would still be captured when the measure is updated in the subsequent quarter, assuming the HCP remains eligible.

Comment: One commenter noted that CMS proposed a COVID–19 Vaccination Coverage among HCP measure in the FY 2022 Inpatient Prospective Payment System (IPPS) proposed rule and stated the numerator would be calculated based on HCP who received a completed vaccination course ''since the vaccine was first available or on a repeated interval if revaccination is recommended.'' The commenter requested CMS provide clarification how evolving vaccine recommendations will be accounted for in the COVID–19 Vaccination Coverage among HCP measure proposed for the SNF QRP. Several other commenters questioned how vaccination boosters would factor into reporting requirements. Commenters stated it would be premature for CMS to adopt the measure because it is unknown how long the COVID–19 vaccination would be effective as well as whether and how often booster shots may be required. They noted that given the evolving nature of the COVID–19 virus, that information could change between the time a person receives a vaccine and the public reporting of the data. Commenters noted that these were important unanswered questions they thought would affect both the design and feasibility of any HCP vaccination

[90] CBS News. More Than 20 States Not Ordering All Available Doses as COVID–19 Vaccinations Slow. Retrieved from *https://www.cbsnews.com/news/covid-19-vaccine-doses-states/.*

[91] Good Rx. From Shortage to Surplus: A Growing Number of U.S. Counties Have Vacant COVID–19 Vaccine Appointments. Retrieved from *https://www.goodrx.com/blog/covid-19-vaccine-surplus-vacant-appointments/.*

measure and would likely result in a change to the measure definition. Several commenters suggested CMS wait until expectations are clarified about maintaining employees' COVID–19 vaccinations.

Response: The COVID–19 Vaccination Coverage among HCP measure is a measure of a completed COVID–19 vaccination course (as proposed in section VI.C.2.e. of the FY 2022 SNF PPS proposed rule). A complete vaccination course may require one or more doses depending on the specific vaccine used. Currently, the need for COVID–19 booster doses has not been established, and no additional doses are currently recommended for HCP.[92] However, we believe that the numerator is sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' and therefore the measure is sufficiently specified to address boosters.

Comment: We received several comments posing questions about the uncertainty the provider community, which we interpret to be SNFs, believe around the future of the COVID–19 vaccination due to the prevalence of misinformation about COVID–19 and the vaccines.

Response: We acknowledge that the science around the SARS–CoV–2 virus continues to evolve. We are still learning how effective the vaccines are against new variants of the virus that causes COVID–19, although current evidence suggests that the COVID–19 vaccines authorized for use in the United States offer protection against most variants currently spreading in the United States.[93] This is one of several reasons we proposed the COVID–19 Vaccination Coverage among HCP measure. The CDC will continue to monitor the effectiveness of the COVID–19 vaccines.

Comment: A number of commenters voiced concern that requiring SNFs to report this information for payment purposes could create incentives for SNF employers to coerce or intimidate HCP who decline the vaccine. They point out that vaccine hesitancy is a real challenge not only among the general public, but also among HCP. They note that some personnel have indicated a preference to wait until the vaccine receives full FDA approval before receiving it. These commenters expressed concern that adding the measure to the SNF QRP conflates the ability of a nursing home to overcome the independent, individual medical choices of its HCP with the ability of the nursing home to provide quality care to the residents living in the facility. Some commenters were concerned that healthcare workers who have not yet received the vaccine or who cannot for various reasons may be let go or have reduced hours based on an employer's desire for higher reporting. They point to the challenges in finding healthcare workers to meet demand, and that requiring vaccines will only make it worse. For these reasons, they believe CMS should delay implementation and public reporting until FY 2023 or remove the measure entirely.

Response: We appreciate that some HCP may have concerns about COVID–19 vaccinations, but the COVID–19 Vaccination Coverage among HCP measure does not mandate or require SNF HCP to complete a COVID–19 vaccination course in order to meet the measure's data reporting requirements. The SNF QRP is a pay-for-reporting program and the number of HCP who have been vaccinated in a SNF does not impact SNF's ability to successfully report the measure. Additionally, we believe it is important that the SNFs report COVID–19 Vaccination Coverage among HCP measure as soon as possible to assess the potential spread of COVID–19 among their HCP and assess the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of SNFs to continue serving their communities throughout the PHE and beyond.

Comment: A few commenters were concerned that if SNFs were found to have ''missing data,'' they would receive a monetary penalty or a reduction in reimbursement.

Response: The SNF QRP is a pay-for-reporting program and the measures under the SNF QRP are tools that measure or quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality health care and/or that relate to one or more quality goals for health care. The rate of vaccination in a SNF is not tied to a SNF's Medicare payment.

To meet the reporting requirements for the COVID–19 Vaccination Coverage among HCP measure, we proposed that a SNF would have to report the cumulative number of HCP eligible to work in the SNF for at least one day during the reporting period and who received a complete vaccination course against SARS–CoV–2. SNFs would have to report data for the measure at least one week per month and could self-select the week. For SNFs that report more than 1 week per month, the last week of the reporting month will be used.

CMS' contractor sends informational messages to SNFs that are not meeting Annual Payment Update (APU) thresholds on a quarterly basis ahead of each submission deadline. Information about how to sign up for these alerts can be found on the SNF QRP Help web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-QRP-Help.*

Comment: A couple commenters expressed concern about unintended consequences and legal risks to their organization if HCP experience an adverse event related to vaccination, and therefore oppose adoption of the COVID–19 Vaccination Coverage among HCP measure into the SNF QRP.

Response: It is unclear what unintended consequences and legal risks the commenters are referring to. The SNF QRP is a pay-for-reporting program, and SNFs are assessed under the program based on whether they have met the SNF QRP's reporting requirements. The COVID–19 Vaccination Coverage among HCP measure does not require HCP to be vaccinated in order for SNFs to successfully report the measure under the SNF QRP.

Comment: One commenter raised concern about the possibility of a double jeopardy that would arise from the interplay of a SNF QRP measure on COVID–19 vaccination and the requirements of the interim final rule with comment period (the May 2021 IFC). They note that under the May 2021 IFC, a nursing home can be cited and receive a civil monetary penalty (CMP) for failure to report COVID–19 vaccination data for a given week, while under the SNF QRP, a SNF may incur a rate reduction for a full calendar year if it fails to meet the reporting requirements. Several other commenters echoed the same concerns.

Response: It is unclear what the commenter means by the term ''double jeopardy'', but we interpret it to mean that the commenter is concerned about being penalized twice for the same data

[92] Centers for Disease Control and Prevention. Vaccine Administration. Available at *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.* Accessed June 25, 2021.

[93] Centers for Disease Control and Prevention. Covid-19 vaccines and new variants. Available at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/work.html#:~:text=COVID%2D19%20vaccines%20and%20new%20variants%20of%20the%20virus&text=Current%20data%20suggest%20that%20COVID,after%20they%20are%20fully%20vaccinated.* Accessed June 25, 2021.

submission requirements. We disagree with the commenter, as the LTC facility requirements of participation at (requirements) at § 483.80(g) and the SNF QRP are two separate requirements. The LTC facility requirements require nursing homes to report weekly on the COVID–19 vaccination status of all residents and staff as well as COVID–19 therapeutic treatment administered to residents. As discussed in section VIII.C.2.e of this final rule, we proposed that SNFs would report the number of eligible HCP who have worked at the facility during 1 week of each month and the number of those HCP who have received a completed COVID–19 vaccination course. Each system has its own methods of validation and carry separate penalties. We proposed the COVID–19 Vaccination Coverage among HCP measure under the SNF QRP.

Comment: One commenter stated they did not support the adoption of the COVID–19 Vaccination Coverage among HCP measure into the SNF QRP because they believe it conflicts with the May 2021 IFC that specifies a similar measure using similar data sources.

Response: As described above, the regulations at § 483.80(g) finalized in the May 2021 IFC are for the LTC facilities' requirements, and are separate from the SNF QRP. The purpose of the proposed COVID–19 Vaccination Coverage among HCP measure is different from the vaccination information reporting requirement in the May 2021 IFC. The proposed SNF QRP COVID–19 Vaccination Coverage among HCP measure will allow for the collection of this data under the SNF QRP and subsequent public reporting of facility-level HCP vaccination rates on Care Compare so that Medicare beneficiaries can make side-by-side facility comparisons to facilitate informed decision making in an accessible and user-friendly manner. The measure's purpose is distinct from those laid out in the May 2021 IFC which are: To update the LTC facilities' requirements to address the issues of resident and staff vaccination education and the reporting of COVID–19 vaccinations and therapeutic treatments to the CDC; to ensure that all LTC facility residents and the staff that care for them are provided ongoing access to vaccination against COVID–19; to assist surveyors to determine individual facilities that may need to have focused infection control surveys; to monitor broader community uptake and to allow the CDC to identify and alert CMS to facilities that may need additional support in regards to vaccine administration and education.

Comment: One commenter stated that since the May 2021 IFC was released, they have been reporting staff and resident vaccination rates weekly via NHSN's Weekly HCP and Resident COVID–19 Vaccination Module. The proposal to add the COVID–19 Vaccination Coverage among HCP measure to the SNF QRP uses the same reporting process but at a different frequency. This commenter recommended CMS align the reporting requirements at § 483.80(g) with the COVID–19 Vaccination Coverage among HCP measure reporting requirements or explain how to manage competing requirements in different rules. Another commenter was unclear which rule they should follow. Another commenter stated they support the requirement in this rule to report monthly but are concerned that once the PHE is lifted, it would be overly burdensome to ask providers to report every week. They requested that CMS respond and explain how to manage competing requirements in different rules.

Response: The requirements finalized at § 483.80(g) are mandatory for participating in Medicare and are separate from the SNF QRP. Each of the requirements is met by reporting through the NHSN's Weekly HCP COVID–19 Vaccination Module. We are clarifying that a SNF that submits four weeks of data to meet the requirements of participation at § 483.80(g) would also meet the data submission requirement for the COVID–19 Vaccination Coverage among HCP for the SNF QRP.

Comment: A number of commenters stated it is premature to begin tracking COVID–19 vaccinations because the COVID–19 vaccines are authorized through an EUA and do not have full FDA approval at this time. One commenter acknowledged that they were confident in the safety and efficacy of the three current vaccines but still finds it to be incongruous to adopt a measure into Federal Quality Reporting Programs that assess the use of a product that has not yet received full Federal approval. Several commenters stated the measure should not be adopted until full approval by FDA across all existing submitted vaccines under EUAs. Another commenter stated that until FDA approves the vaccines, they do not have control over the vaccination status of their employees.

Response: The COVID–19 vaccines are authorized by the FDA for use through an Emergency Use Authorization (EUA). We refer readers to the FDA website for additional information related to FDA process for evaluating an EUA request at *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.* The Equal Employment Opportunity Commission (EEOC) released updated and expanded technical assistance on May 28, 2021.[94] Specifically the EEOC stated the Federal equal employment opportunity (EEO) laws do not prevent an employer from requiring all employees physically entering the workplace to be vaccinated for COVID–19, so long as the employer complies with the reasonable accommodation provisions of the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964 and other EEO considerations. In addition, FDA is closely monitoring the safety of the COVID–19 vaccines authorized for emergency use. We believe that due to the continued PHE and the ongoing risk of infection transmissions in the SNF population, the benefits of finalizing this measure in this year's final rule are essential for patient safety.

Comment: We received numerous comments requesting that CMS delay the adoption of the COVID–19 Vaccination Coverage among HCP measure until it has received NQF endorsement. Commenters were concerned that since the measure has not been fully specified, tested, or endorsed by the NQF, then it may not be thoroughly tested and vetted, and may impact patients' certainty that the data they rely on are reliable. Other commenters included language from the Post-Acute Care/Long-term Care Workgroup (Workgroup) of the Measures Application Partnership (MAP) meeting transcript to support their position. They all urged the agency, in addition to seeking NQF endorsement, to fully develop and test the measure for reliability and validity before implementing it in the SNF QRP.

Response: Given the novel nature of the SARS–CoV–2 virus, and the significant and immediate health risk it poses in SNFs, we believe it is necessary to adopt this measure as soon as possible. Additionally, given the results from CDC's preliminary validity testing of the data elements required for the measure numerator (described further in section VI.C.2.c. of the FY 2022 SNF PPS proposed rule), the alignment between the denominator of this measure and the denominator of the Influenza Vaccination among HCP

[94] U.S. Equal Employment Opportunity Commission. What You Should Know About COVID–19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Available at *https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.* Accessed June 25, 2021.

measure (NQF#0431), and the MAP's determination that the measure has face validity, CMS proposes the COVID–19 Vaccination Coverage among HCP measure beginning with the FY 2023 SNF QRP. As noted previously, the CDC, in collaboration with CMS, are planning to submit the measure for consideration in the NQF Fall 2021 measure cycle.

Comment: A commenter stated they did not believe CMS had the statutory authority to add the COVID–19 Vaccination Coverage among HCP measure to the SNF QRP. The commenter went on to state that section 1899B(a)(1)(B) of the IMPACT Act is intended to support interoperable patient care measures to compare outcomes across post-acute provider settings. They do not believe the proposed staff vaccination measure is a patient care measure.

Response: We believe the commenter is referring to section 1899B(a)(1)(B) of the Act. We disagree with the commenter that we lack the statutory authority to propose this measure. Section 1899B(d)(1) of the Act requires the Secretary to specify resource use and other measures. Section 1899B(a)(1)(B) requires, in part, that data on resource use and other measures under section 1899B(d)(1) of the Act facilitate coordinated care and improve Medicare beneficiary outcomes. Remaining COVID–19 free while receiving SNF care is critically important for Medicare beneficiaries, and thus a measure that increases the likelihood of this outcome would be considered a patient care measure. As illustrated in Medicare claims and encounter data,[95] the number of Medicare beneficiaries hospitalized with COVID–19 in the last week of December 2020 was over 50,000, and the number of COVID–19 cases exceeded 4.3 million as of April 24, 2021. We believe that the toll the COVID pandemic has taken on Medicare beneficiaries demonstrates the need for increased action to mitigate the effects of the ongoing pandemic.

Section 1899B(a)(1)(B) of the Act also requires, in part, that data on resource use and other measures under section 1899B(d)(1) of the Act be standardized and interoperable so as to allow for the exchange of such data among PAC providers, including SNFs. We have proposed the COVID–19 Vaccination Coverage among HCP measure under the IRF QRP in the FY 2022 IRF PPS proposed rule (86 FR 19105 through 19108), and the LTCH QRP under the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25610 through 25613) consistent with these requirements. Further, this measure would facilitate patient care and care coordination during the discharge planning process. A discharging hospital or facility, in collaboration with the patient and family, could use this measure to coordinate care and ensure patient preferences are considered in the discharge plan. Patients at high risk for negative outcomes due to COVID–19 (perhaps due to underlying conditions) can use healthcare provider vaccination rates when they are selecting a SNF for next-level care.

Comment: A commenter noted that CMS, to date, has restricted all measures developed under section 1899B(a)(1)(B) of the Act to include only Medicare beneficiaries accessing their post-acute care benefit to align with the other post-acute care settings. They recommended not finalizing the COVID–19 Vaccination Coverage among HCP measure because it is not restricted to staff providing care to post-acute care residents and would be nearly impossible to collect.

Response: To date, we have developed measures under section 1899B of the Act to include only Medicare beneficiaries accessing their post-acute care benefit. We proposed the measure as specified by the CDC, which includes all of the staff within the facility because all staff within the facility place patients receiving post-acute care (including SNF residents) at risk for getting COVID–19. This is true whether or not they are providing direct care to post-acute care patients.

In regard to the comment about the near impossibility of collecting information exclusively among staff providing care to post-acute care residents, we agree. This is one of the reasons why the measure is specified to capture the information on all healthcare staff in the SNF, including personnel, such as dietary staff, administrators, or social workers. While it may be easy to identify SNF direct care staff who provide care to SNF residents, it would be nearly impossible to ensure other personnel, such as dietary staff, administrators, or social workers, interact exclusively with SNF patients.

Comment: We heard from several commenters who found the COVID–19 Vaccination Coverage measure among HCP was not aligned with the Influenza Vaccination Coverage among HCP (NQF #0431) measure as CMS stated in the proposed rule. They pointed out that circumstances around the use of the COVID–19 vaccine are not entirely comparable to those of the influenza vaccine.

Response: We agree that there are key differences between the Influenza Vaccination among HCP measure and the COVID–19 Vaccination Coverage among HCP measure. We acknowledge that even though the CDC modeled the COVID–19 Vaccination Coverage among HCP measure after the Influenza Vaccination among HCP measure, FDA-approved influenza vaccines and the authorized COVID–19 vaccines differ in multiple ways. The reporting requirements for the numerator of the COVID–19 Vaccination Coverage among HCP measure that one commenter listed are due to the fact that some COVID–19 vaccines require two doses to reach full vaccination status, while some COVID–19 vaccines require only one dose. The measures are aligned with respect to the reporting mechanism used to report data (the NHSN) and key components of the measure specifications (for example, the definition of the denominator), but the measures allow for important differences to reflect the reality that the circumstances around vaccine administration (that the commenter points out) are not identical.

Comment: Several commenters pointed to the fact that SNFs have many questions about the specifics of the COVID–19 Vaccination Coverage among HCP measure such as what the long-term plans for using the measure in the SNF QRP are. Another commenter thought the measure seemed unnecessary based on the current vaccination push and the fact that due to the Federal Vaccination Schedule, healthcare workers would already have received the vaccination. This commenter did not believe it addressed many of the unknowns still ahead regarding the virus.

Response: We interpret the commenter's reference to the ''Federal Vaccination Schedule'' to be referring to the eligibility criteria during the initial rollout of the COVID–19 vaccine. When the U.S. supply of COVID–19 vaccine was limited, CDC provided recommendations to Federal, state, and local governments about who should be vaccinated first. While CDC made recommendations for who should be offered the COVID–19 vaccines first, each state had its own plan. CMS acknowledges that healthcare workers were given priority in receiving the vaccine, but as reported by Medscape

[95] Medicare COVID–19 Data Snapshot Overview. Available at *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.* Accessed July 12, 2021.

Medical News on June 28, 2021,[96] Federal data show that one in four hospital workers across the United States are still unvaccinated, and only one in every three hospital workers are vaccinated in the nation's 50 largest health systems. We believe it is critical to measure staff vaccination rates among SNFs even as vaccinations become more common, especially in light of the vaccine hesitancy other comments have pointed out.

In response to the comment asking about the long-term plans for using the measure, as described in sections VII.C.2.e and VII.H.3. of this final rule, we proposed to adopt the COVID–19 Vaccination Coverage among HCP measure into the SNF QRP and publicly report on SNF performance. Once a measure is adopted under the SNF QRP, the measure will remain in effect until CMS proposes that it be removed, suspended, or replaced. We refer readers to the FY 2016 SNF PPS final rule (80 FR 46431 through 46432) for details on this policy.

Comment: A commenter questioned whether the COVID–19 Vaccination among HCP measure aligned with the Merit-based Incentive Payment System (MIPS) measure that was reviewed by the MAP and assesses patients who received at least one dose (in addition to a complete course).

Response: We understand the commenter to be questioning whether this measure is similar to the measure considered for another quality reporting program, the Merit-based Incentive Payment System (MIPS) for clinicians. If so, MUC—0045, the SARS–Co–V–2 Vaccination by Clinician measure differs from the COVID–19 Vaccination Coverage among HCP measure. Most notably, the SARS–CoV–2 Vaccination by Clinician measure assesses the proportion of patients who received at least one SARS–CoV–2 vaccination while the COVID–19 Vaccination Coverage among HCP measure assesses the proportion of HCP who complete a SARS–CoV–2 vaccination course.

Comment: Commenters pointed out that the Influenza Vaccination Coverage among HCP (NQF #0431) measure utilizes providers working in the facility for the denominator whereas the proposed COVID–19 metric utilizes providers eligible to work in the facility. Several commenters requested that CMS revise the COVID–19 Vaccination Coverage among HCP measure denominator to include eligible providers who have worked at the facility during the period being measured, similar to the influenza measure. The commenters believe this would be important due to differences across states as to whom would be considered ''eligible'' to work due to laws such as the Family Medical Leave Act (FMLA) and state-level laws associated with defining employee status.

Response: As described in section VII.G.3. of this final rule, we proposed the COVID–19 Vaccination Coverage among HCP measure to include HCP who work regularly in the SNF, and to require SNFs to use the specifications and data collection tools for the proposed COVID–19 Vaccination Coverage among HCP as required by CDC as of the time that the data are submitted. Subsequent to the publication of the FY 2022 SNF PPS proposed rule on April 8, 2021, the CDC released the Instructions for Completion of the Weekly Healthcare Personnel COVID–19 Vaccination Cumulative Summary for Long-Term Care Facilities (57.219, REV3) which are available at *https://www.cdc.gov/nhsn/forms/instr/57.219-toi-508.pdf* . The document defines HCP eligible to have worked to include those scheduled to work in the facility at least one day every week. The document instructs SNFs to count any HCP working part of a day, as well as those that may be on temporary leave during the week of data collection. Temporary leave was further defined as less than or equal to 2 weeks in duration. Because the measurement period covered by the Influenza Vaccination Coverage among HCP (NQF #0431) measure is quite long (the entire 6 month influenza season), such absences do not impact the Influenza Vaccination Coverage among HCP (NQF #0431) measure denominator. However, in order to provide more timely measurement of COVID–19 vaccination coverage while also reducing the burden of data collection for SNFs, we proposed the measurement period of the COVID–19 Vaccination among HCP measure to be only one week, considerably shorter than the time period covered by the Influenza Vaccination Coverage among HCP (NQF #0431) measure, and a number of regularly working HCP who would be counted within the 6-month period of the Influenza Vaccination Coverage Measure may be absent during this shortened period. Therefore, HCP who regularly work in the SNF, but may be temporarily absent for up to 2 weeks, are still to be included in the COVID–19 Vaccination Coverage among HCP measure as these regular workers will be working during other weeks of the reporting month. While differences may exist across states in employment eligibility definitions, the CDC definition for purposes of this measure includes HCP eligible to have worked and scheduled to work in the facility at least one day during the week of data collection. This approach provides a consistent definition of eligibility which is necessary for national and regional data analyses.

Comment: One commenter provided several recommendations for revising the denominator of the COVID–19 Vaccination Coverage among HCP measure. They stated there are several contraindications or exclusions that go beyond allergies to the ingredients of the vaccine, and therefore these persons should be excluded from the denominator as well. They specifically point to individuals who have been vaccinated within the last 2 weeks and individuals who have received monoclonal antibody or another COVID–19 therapy and individuals with an active COVID–19 infection as persons who should be excluded from the measure. They also urged CMS to ensure that the regulatory language has the flexibility to accommodate these and any future changes.

Response: We thank the commenter for the recommendations. The CDC website describes a number of clinical considerations for the use of COVID–19 vaccines on its website at *https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf.* These considerations are separate from the contraindications to the vaccines. Contraindications to the vaccines can be found in the FDA Fact Sheets for the authorized COVID–19 vaccines, which are accessible through the FDA web pages for those vaccines.[97] [98] [99] Therefore, we disagree with the commenter and do not believe the definition of the denominator needs to be changed.

Comment: One commenter stated that if CMS proceeded with finalizing the measure, they strongly encourage the agency to consider including all HCP in the denominator, at least for an initial reporting period and to allow for

[96] Medscape. Disturbing Number of Hospital Workers Still Unvaccinated. Available at *https://www.medscape.com/viewarticle/953871.* Accessed July 13, 2021.

[97] Pfizer-BioNtech COVID–19 vaccine. Available at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.*

[98] Moderna COVID–19 vaccine. Available at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine.*

[99] Janssen COVID–19 vaccine. Available at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine.*

consistent cross-provider reporting and accurate measurement and comparisons. They also stated CMS should include a clear explanation in public reporting that the measure includes HCP with contraindications.

Response: We interpret the commenter to be stating that the denominator should include HCP with and without contraindications to the vaccination. We believe that excluding HCP with contraindications from the measure strikes an appropriate balance between obtaining accurate estimates of vaccine rates among HCP within SNFs and not holding a SNF accountable for HCP with a COVID–19 vaccination contraindication, as the number of HCP with contraindications or exclusions from vaccination is expected to be low.

Comment: One commenter raised a question about guidance to state survey agencies found in QSO–21–19–NH.[100] In it, they pointed out a discrepancy in how CMS defined ''staff'' for COVID–19 vaccination reporting and the definition provided for HCP under the proposed quality measure. They are concerned about the confusion it will cause providers.

Response: We interpret the commenter's point to be about the definitions for purposes of reporting data to the NHSN to meet the LTC facility requirements at § 483.80(g) and the requirements for the SNF QRP. Our May 11, 2021 guidance, QSO–21–19–NH, defines ''staff'' to mean individuals who work in the facility on a regular (that is, at least once a week) basis, including individuals who may not be physically in the LTC facility for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. This also includes individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, or volunteers, who are in the facility on a regular basis, as the vaccine is available. The instructions for completing the NHSN Weekly Healthcare Personnel COVID–19 Vaccination Cumulative Summary for Long-Term Care Facilities [101] defines ''Number of HCP that were eligible to have worked at this facility for at least 1 day during the week of data collection'' to include employees, contractors, or students, trainees, and volunteers who are scheduled to work in the facility at least one day every week. Working any part of a day is considered as working 1 day. HCP are to be included even if they are on temporary leave during the week of data collection. Temporary leave is defined as less than or equal to 2 weeks in duration. Examples of temporary leave may include sick leave or vacation. In instances where temporary leave extends past 2 weeks, the healthcare worker should not be included in question #1 for the current week of data collection. We believe the NHSN instructions to be a clarification of the QSO–21–19–NH memo, provided to facilitate completion of the module in a consistent manner.

Comment: One commenter had questions on what ''fully vaccinated'' meant.

Response: The term ''fully vaccinated'' is not used in the proposed COVID–19 Vaccination Coverage among HCP measure. We proposed the numerator for the COVID–19 Vaccination Coverage among HCP measure to include a complete vaccination course as defined in section VI.C.2.e. of the FY 2022 SNF PPS proposed rule. We refer the commenter to the CDC's website where the term ''fully vaccinated'' is defined at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html.*

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2023 SNF QRP as proposed.

3. Update to the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure Beginning With the FY 2023 SNF QRP

We proposed to update the Transfer of Health Information to the Patient—Post-Acute Care (PAC) measure denominator to exclude residents discharged home under the care of an organized home health service or hospice. This measure assesses for and reports on the timely transfer of health information, specifically transfer of a medication list. We adopted this measure in the FY 2020 SNF PPS final rule (84 FR 38761 through 38764) beginning with the FY 2022 SNF QRP. It is a process measure that evaluates for the transfer of information when a resident is discharged from his or her current PAC setting to a private home/apartment, board and care home, assisted living, group home, transitional living, or home under the care of an organized home health service organization or hospice.

This measure, adopted under section 1899B(c)(1)(E) of the Act, was developed to be a standardized measure for the IRF QRP, LTCH QRP, SNF QRP, and Home Health (HH) QRP. The measure is calculated by one standardized data element that asks, ''At the time of discharge, did the facility provide the resident's current reconciled medication list to the resident, family, and/or caregiver?'' The discharge location is captured by items on the Minimum Data Set (MDS).

Specifically, we proposed to update the measure denominator. Currently, the measure denominators for both the TOH-Patient and the TOH-Provider measure assess the number of residents discharged home under the care of an organized home health service organization or hospice. In order to align the measure with the IRF QRP, LTCH QRP and HH QRP and avoid counting the resident in both TOH measures in the SNF QRP, we proposed to remove this location from the definition of the denominator for the TOH-Patient measure. Therefore, we proposed to update the denominator for the TOH-Patient measure to only discharges to a private home/apartment, board and care home, assisted living, group home, or transitional living. For additional technical information regarding the TOH-Patient measure, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Final-Specifications-for-SNF-QRP-Quality-Measures-and-SPADEs.pdf.*

We invited public comment on our proposal to update the denominator of the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure (TOH-Patient-PAC measure) beginning with the FY 2023 SNF QRP.

The following is a summary of the public comments received on our proposal to update the denominator of the TOH Information to the Patient—PAC measure beginning with the FY 2023 SNF QRP and our responses:

Comment: We received overwhelming support for our proposal to update the TOH-Patient-PAC measure's denominator to remove the inclusion of ''home under care of an organized home health service organization or hospice.'' Provider and trade associations agreed that the update will reduce denominator redundancy in the two TOH

[100] CMS. Interim Final Rule—COVID–19 Vaccine Immunization Requirements for Residents and Staff. Retrieved from *https://www.cms.gov/files/document/qso-21-19-nh.pdf.*

[101] NHSN. Instructions for Completion of the Weekly Healthcare Personnel COVID–19 Vaccination Cumulative Summary for Long-Term Care Facilities (57.219, REV 3). Retrieved from *https://www.cdc.gov/nhsn/forms/instr/57.219-toi-508.pdf.*

Information—PAC measures. One commenter stated that the update will provide a refined measure that more accurately accounts for the SNF's performance in this area. A few commenters also were appreciative of CMS' review of measures to reduce unnecessary provider burden.

Response: We appreciate the commenters' support.

Comment: A few commenters stated that it was premature to introduce this measure beginning with the FY 2023 SNF QRP since the assessment data would not be available to calculate performance. Since the TOH-Patient measure requires the use of MDS item A2105—Discharge Status, an item that is currently not available on the assessment tool used by SNFs (the MDS V1.17.2) commenters did not believe the information could be collected. They noted that in the IFC published on May 8, 2020 entitled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (85 FR 27550), CMS delayed collection of MDS item A2105—Discharge Status until a particular point in time after the PHE has ended. Therefore, commenters requested that CMS consider reinstating the delay of this measure as originally stated in the May 8, 2020 IFC.

Response: We acknowledge that the current version of the MDS, MDS 3.0 v1.17.2, which SNFs use to submit data to meet the requirements of the SNF QRP, does not currently include the data elements needed to report the TOH-Patient-PAC measure which we finalized for data collection beginning October 1, 2020 (84 FR 38761 through 38764). In the May 8, 2020 IFC (85 FR 27550), we delayed data collection for certain SNF QRP items, including the MDS item A2105, until the October 1 date that is at least two full fiscal years after the end of the PHE for COVID–19. However, because it is uncertain when the PHE will end, we proposed to make the measure denominator specification change effective FY 2023. Therefore, when the PHE ends, and the MDS item A2105—Discharge Status collection begins, the measure update would already be in place.

Comment: One commenter opposed our proposal to update the denominator specifications for the TOH-Patient-PAC measure. The commenter was concerned that revising the denominator would remove the responsibility of the SNF to provide the medication list to the ''patient, family, or caregiver'' when the patient is transferred to home health or hospice providers. The commenter believes that the current medication list should be provided to the resident and family/caregivers regardless of the discharge location because family caregivers are often involved in assisting the person they are caring for with their medications.

Response: The TOH-Patient-PAC data element under the TOH-Patient-PAC measure asks about the transfer of a reconciled medication list to the patient, family, and/or caregiver. While residents discharged home under the care of an organized home health service organization or hospice will no longer be included in the denominator of the TOH-Patient-PAC measure to reduce redundancy with the TOH-Provider-PAC measure, we acknowledge the importance of family and/or caregivers and encourage care collaboration between the SNF and the family or caregiver when authorized by the patient. SNFs are required under § 483.21(c)(2)(iii) to provide a resident at discharge with a discharge summary that includes, but is not limited to, reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter). We refer the commenter to the FY 2020 SNF PPS final rule (84 FR 38761 through 38764) for additional information about this process measure.

Comment: One commenter requested clarity on the measure and the problem CMS is aiming to resolve.

Response: We refer the reader to the FY 2020 SNF PPS proposed and final rules (84 FR 17638 through 17643 and 84 FR 38761 through 38764, respectively) where the TOH-Patient-PAC measure was proposed and finalized. For additional technical information regarding the TOH-Patient-PAC measure, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Final-Specifications-for-SNF-QRP-Quality-Measures-and-SPADEs.pdf.*

We refer the reader to section VI.C.3. of the FY 2022 SNF proposed rule where we described the issue this proposal addresses. Currently, the measure denominators for both the TOH-Patient and the TOH-Provider measure assess the number of residents discharged home under the care of an organized home health service organization or hospice. In order to align the measure with the IRF QRP, LTCH QRP and HH QRP and avoid counting the resident in both TOH measures in the SNF QRP, we proposed to remove this location from the definition of the denominator for the TOH-Patient measure.

After careful consideration of the public comments we received, we are finalizing our proposal to update the denominator for the Transfer of Health (TOH) Information to the Patient–Post-Acute Care (PAC) measure under section 1899B(c)(1)(E) of the Act beginning with the CY 2023 SNF QRP as proposed.

D. SNF QRP Quality Measures Under Consideration for Future Years: Request for Information (RFI)

We solicited input on the importance, relevance, appropriateness, and applicability of each of the measures and concepts under consideration listed in Table 25 for future years in the SNF QRP.

TABLE 25: Future Measures and Measure Concepts Under Consideration for the SNF QRP

Assessment-Based Quality Measures and Measure Concepts
Frailty
Patient reported outcomes
Shared decision making process
Appropriate pain assessment and pain management processes
Health equity

We received several comments on this RFI, which are summarized below:

Comment: Most commenters supported the inclusion of all the proposed measures listed in Table 25. One commenter stated that all of the measures and measure concepts are important and relevant for assessing quality of care delivered to SNF patients.

Many commenters supported the concept of frailty, and one commenter stated that frailty assessments provide a means of identifying older adults most vulnerable to adverse health outcomes.

Commenters were generally supportive of the measure concept for shared decision-making process and pointed out it was important to ensuring care delivered in a SNF was in line with the person's goals and values. Other commenters questioned how it could be captured in the SNF QRP. One commenter shared concerns about using shared decision-making as a quality measure, and recommended CMS only use claims-based quality measures.

Several commenters supported the concept of patient reported outcomes (PROs) while others were uncertain what CMS intends with the term patient reported outcomes. One commenter stressed the importance of PROs since they determine outcomes based on information obtained directly from patients, and therefore provide greater insight into patients' experience of the outcomes of care. Another commenter echoed that and stated that patients and caregivers are the best sources of information reflecting the totality of the patient experience.

Several commenters were supportive of the inclusion of pain management quality measures because pain is a common occurrence with SNF residents and may be under recognized and undertreated. One commenter stated that the development of an appropriate pain assessment and pain management processes measure is a clinically challenging domain that requires much more attention. Another commenter agreed stating that it is an area to focus on since given the current opioid epidemic, appropriate pain management has become a delicate and challenging subject.

Commenters were generally supportive of the concept of health equity in quality measurement. They agree that closing the health equity gap is essential to ensure optimal health services and outcomes to all Americans regardless of individual characteristics, and one commenter noted that health equity is a vital quality measure to ensure that long term care is equal for all residents.

A couple of commenters encouraged CMS to remove topped out measures and low occurrence measures to ensure it remains relevant to quality and performance. Commenters also suggested other concepts for quality measurement in the SNF QRP such as: Nutritional status, cognitive status, and advance directives.

Response: We appreciate the input provided by commenters. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this input to inform our future measure development efforts.

E. Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Quality Programs—RFI

1. Solicitation of Comments

We sought input on the following steps that would enable transformation of CMS' quality measurement enterprise to be fully digital.

- What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?
- How do you currently share information with other providers?
- In what ways could we incentivize or reward innovative uses of health information technology (IT) that could reduce burden for post-acute care settings, including but not limited to SNFs?
- What additional resources or tools would post-acute care settings, including but not limited to SNFs, and health IT vendors find helpful to support the testing, implementation, collection, and reporting of all measures using FHIR standards via secure APIs to reinforce the sharing of patient health information between care settings?
- Would vendors, including those that service post-acute care settings, such as SNFs, be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would align standards for quality measure data collection across care settings to improve care coordination, such as sharing patient data via secure FHIR API as the basis for calculating and reporting digital measures?

While we will not be responding to specific comments submitted in response to this RFI in this final rule, we appreciate all of the comments on and interest in this topic. We believe that this input is very valuable in the continuing development of our transition to digital quality measurement in CMS quality programs. We will continue to take all comments into account as we develop future regulatory proposals or future subregulatory policy guidance for our digital quality measurement efforts.

F. Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs—RFI

1. Solicitation of Public Comment

Under authority of the IMPACT Act and section 1888(e)(6) of the Act, we solicited comment on the possibility of revising measure development, and the collection of other Standardized Patient Assessment Data Elements that address gaps in health equity in the SNF QRP. Any potential health equity data collection or measure reporting within a CMS program that might result from public comments received in response to this solicitation would be addressed through a separate notice-and-comment rulemaking in the future.

Specifically, we invited public comment on the following:

- Recommendations for quality measures, or measurement domains that address health equity, for use in the SNF QRP.
- As finalized in the FY 2020 SNF PPS final rule (84 FR 38805 through 38817), SNFs must report certain standardized patient assessment data elements on SDOH, including race, ethnicity, preferred language, interpreter services, health literacy, transportation and social isolation.[102] We solicited guidance on any additional items, including standardized patient assessment data elements that could be used to assess health equity in the care of SNF residents, for use in the SNF QRP.
- Recommendations for how CMS can promote health equity in outcomes among SNF residents. For example, we are interested in feedback regarding whether including facility-level quality measure results stratified by social risk factors and social determinants of health (for example, dual eligibility for Medicare and Medicaid, race) in confidential feedback reports could allow facilities to identify gaps in the quality of care they provide. (For example, methods similar or analogous to the CMS Disparity Methods [103] which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures, which are currently included in the Hospital Readmission Reduction

[102] *https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html.*

[103] *https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html.*

Program (see 84 FR 42496 through 42500)).

- Methods that commenters or their organizations use in employing data to reduce disparities and improve patient outcomes, including the source(s) of data used, as appropriate.
- Given the importance of structured data and health IT standards for the capture, use, and exchange of relevant health data for improving health equity, the existing challenges providers' encounter for effective capture, use, and exchange of health information, including data on race, ethnicity, and other social determinants of health, to support care delivery and decision making.

While we will not be responding to specific comments submitted in response to this Health Equity RFI in this final rule, we appreciate all of the comments and interest in this topic. We will continue to take all concerns, comments, and suggestions into account as we continue work to address and develop policies on this important topic. It is our hope to provide additional stratified information to providers related to race and ethnicity if feasible. The provision of stratified measure results will allow PAC providers to understand how they are performing with respect to certain patient risk groups, to support these providers in their efforts to ensure equity for all of their patients and to identify opportunities for improvements in health outcomes.

G. Form, Manner, and Timing of Data Submission Under the SNF QRP

1. Background

We refer readers to the regulatory text at 42 CFR 413.360(b) for information regarding the current policies for reporting SNF QRP data.

2. Schedule for Data Submission of the SNF HAI Measure Beginning With the FY 2023 QRP

The SNF HAI measure, which we discuss in section VII.C.1. of this final rule, is a Medicare FFS claims-based measure. Because claims-based measures can be calculated based on data that have already been submitted to the Medicare program for payment purposes, no additional information collection would be required from SNFs. We proposed to use 1 year of FY 2019 claims data (October 1, 2018 through September 30, 2019) for the FY 2023 SNF QRP. We proposed to use FY 2019 data to calculate this measure because it is the most recent fiscal year of data that has not been exempted due to the PHE. Beginning with the FY 2024 SNF QRP, compliance with APU reporting requirements would use FY 2021 claims data (October 1, 2020 through September 30, 2021) and advance by one FY with each annual refresh. Due to the fact that Q1 and Q2 2020 data were excepted by CMS related to the COVID–19 PHE, these quarters of data would not be used for purposes of the QRP. For information on public reporting of the SNF HAI measure, we refer you to Table 29 in section VII.H.4.c. of this final rule.

We invited public comment on this proposal.

The following is a summary of the public comments received on the proposed Schedule for Data Submission of the SNF HAI measure beginning with the FY 2023 QRP and our responses:

Comment: One commenter was supportive of the measure's schedule for data submission.

Response: We thank this commenter for their support of the SNF HAI data submission schedule.

Comment: Another commenter supported the collection of SNF HAI data, but does not want CMS to report it publicly until the PHE has expired.

Response: We thank this commenter for their support. Any comments related to SNF HAI public reporting will be addressed in section VII.H.2. of this final rule.

After careful consideration of the public comments we received, we are finalizing the proposed schedule for data submission of the SNF HAI measure beginning with the FY 2023 SNF QRP as proposed.

3. Method of Data Submission for COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure

As discussed in section VII.C.2 of this final rule, we proposed to require that SNFs submit data on the COVID–19 Vaccination Coverage among HCP measure through the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based surveillance system maintained by the CDC that can be utilized by all types of healthcare facilities in the United States, including acute care hospitals, long-term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and SNFs. The NHSN enables healthcare facilities to collect and use vaccination data, and information on other adverse events. NHSN collects data via a Web-based tool hosted by the CDC (*http://www.cdc.gov/*). The NHSN is provided free of charge. We proposed for SNFs to submit the data needed to calculate the COVID–19 Vaccination Coverage among Healthcare Personnel measure using the NHSN's standard data submission requirements. CDC/NHSN requirements include adherence to training requirements, use of CDC measure specifications, data element definitions, data submission requirements and instructions, data submission timeframes, as well as NHSN participation forms and indications to CDC allowing CMS to access data for this measure for the SNF quality reporting program purposes. Detailed requirements for NHSN participation, measure specifications, and data collection can be found at *http://www.cdc.gov/nhsn/*. We proposed to require SNFs to use the specifications and data collection tools for the proposed COVID–19 Vaccination Coverage among Healthcare Personnel measure as required by CDC as of the time that the data are submitted.

We invited public comment on this proposal. The following is a summary of the public comments received on the proposed Method of Data Submission for COVID–19 Vaccination Coverage among Healthcare Personnel measure and our responses:

Comment: One commenter requested that CMS provide further information on how reporting to a system maintained by the CDC would be shared with CMS for purposes of determining SNF QRP reporting compliance. They questioned how the SNF QRP compliance rate would be calculated since the measure is not submitted through the MDS. Another commenter recommended the use of the COVID–19 Module of the NHSN to report healthcare employee vaccination rates, rather than requiring a separate reporting process through the SNF QRP.

Response: We interpret the commenter to be referring to the SNF QRP reporting requirements for the SNF Annual Payment Update (APU). As explained in section VII.G.3. of this final rule, the mechanism through which the data for calculating the COVID–19 Vaccination Coverage among HCP measure would be the Weekly Healthcare Personnel COVID–19 Vaccination Cumulative Summary for Long-Term Care Facilities Module [104] of the NHSN. There is no ''separate'' submission system. The NHSN collects the data submitted by SNFs, calculates the summary score, and transmits the information to CMS on a quarterly basis. CMS would use that information to determine whether a SNF has met the

[104] *https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html.*

SNF QRP reporting requirements for the COVID–19 Vaccination among HCP measure.

Comment: One commenter raised concerns about implementing a measure based on NHSN data. They explained that SNFs have experienced problems in the past year using the NHSN for reporting COVID–19 related data because they were unaware that they had made errors. They stated there was no process in place for SNF providers to receive feedback on data submissions and correct any errors before the data was made public and assessed. Given the importance of identifying potential errors and making corrections, they are concerned SNFs will be unfairly penalized.

Response: SNFs will have access to provider reports on their NHSN measure performance prior to the submission deadline. Additionally, CMS' contractor sends informational messages to SNFs that are not meeting Annual Payment Update (APU) thresholds on a quarterly basis ahead of each submission deadline. Information about how to sign up for these alerts can be found on the SNF QRP Help web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-QRP-Help.*

Comment: Several commenters expressed concerns about the administrative burden associated with reporting of the measure through NHSN and other systems. They pointed to other reporting systems being used around the country and stated that this would be duplicative reporting. Several commenters referenced the Department of Health and Human Services TeleTracking system, and various state agencies and databases. They stated that having to utilize these systems in addition to the NHSN and its reporting period utilizes additional resources and will require multiple tracking strategies to keep up. They urged CMS to use data from these systems without requiring additional data collection in the NHSN.

Response: The TeleTracking system was one system that was used to manage the critical first months of the PHE for COVID–19, as it was critical that the Federal Government received data to facilitate planning, monitoring, and resource allocation during the COVID–19 Public Health Emergency (PHE). The TeleTracking system collects a number of data points, such as ventilators in the facility, ventilators in use, ICU beds available and ICU beds occupied. However, the TeleTracking system was not used for the SNF QRP. We proposed to use the NHSN COVID–19 Modules for tracking COVID–19 vaccination Coverage among HCP across all sites of service, including SNFs as most of the state Immunization Information Systems do not include the information needed to calculate the COVID–19 Vaccination Coverage among HCP. Additionally, the CDC has developed a Data Tracking Worksheet to assist SNFs collect information for the COVID–19 Vaccination Coverage among HCP measure. After entering the COVID–19 vaccination data for each HCP into the Tracking Worksheet and selecting a week, the data to be entered into the NHSN would automatically be calculated on the Reporting Summary.[105]

Comment: One commenter encouraged CMS to evaluate both methods of how data are submitted (that is, the TeleTracking system and the NHSN) and select just one standardized data reporting system and process. This commenter was in favor of using the NHSN to report the COVID–19 Vaccination Coverage among HCP measure because all care settings are using it to report the Influenza Vaccination Coverage measure among HCP and discontinuing COVID–19 vaccination reporting to the HHS tracking system.

Response: We proposed using the NHSN COVID–19 Modules for tracking COVID–19 Vaccination Coverage among HCP across all sites of service, including SNFs because most of the state Immunization Information Systems do not include the information needed to calculate the COVID–19 Vaccination Coverage among HCP measure.

Comment: A few commenters commented on CMS's statement that the COVID–19 Vaccination Coverage among HCP measure was modeled after the Influenza Vaccination Coverage among HCP measure. They believe there are key differences between the two measures, such as how the vaccines are administered and data are collected. Another provider listed the different reporting requirements for the numerator for the COVID–19 vaccination as compared to the influenza vaccination.

Response: We acknowledge that there are implementation differences between the two measures, even though the CDC modeled the COVID–19 Vaccination Coverage among HCP measure after the Influenza Vaccination Coverage among HCP measure. It is true that the influenza vaccine and the COVID–19 vaccine are not identical, and therefore the administration of these vaccines will not be identical. The key differences between the reporting requirements for the numerator of the COVID–19 Vaccination Coverage among HCP measure that the one commenter listed out are due to the fact that 2 of the 3 available COVID–19 vaccines require 2 doses to reach full vaccination status, and the 3rd available COVID–19 vaccine requires only 1 dose.

Comment: One commenter stated that the reporting burden for the COVID–19 Vaccination Coverage among HCP measure would be high since certain health care settings, including SNFs, do not currently use the NHSN to report data for the SNF QRP. Adopting the measure would require adjustments in workflow for which CMS would need to provide significant technical support.

Response: We disagree with the commenter, as SNFs are currently required to submit COVID–19 HCP vaccination data through the CDC's NHSN Long-term Care Facility COVID–19 Module of the NHSN. We refer readers to § 483.80(g). Therefore we believe there will be no additional burden imposed with the adoption of the SNF QRP measure.

Comment: One commenter attributed the burden of reporting to the fact that the commenter keeps employee health records separate from their electronic health records (EHRs) due to health privacy concerns. Other commenters attributed the burden of reporting to the fact that they cannot or have not routinely collected recorded information about medical contraindications or the reason for the employees' declination in their employee health records. They stated that because the indications and contraindications for receiving the vaccine have changed frequently, and ongoing findings and studies will continue to do so, collecting this information will be even more difficult to track. One commenter stated it will be challenging for providers to obtain the full count of adult students/trainees and volunteers associated with the healthcare system, as these individuals are not always captured or identified as such in their HR databases. Therefore attempting to identify, collect, and extract data on employee vaccinations are inherently difficult and burdensome.

Response: SNFs have experience tracking information and collecting data to inform their care approaches and business practices and have been collecting information related to COVID–19 infections and vaccinations. While SNFs will not have the burden of

[105] Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel at *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.*

registering and learning how to use the NHSN, we acknowledge there will be burden with collecting the required information. However, we believe it will be minimal because SNFs already have experience successfully reporting information using the NHSN reporting modules. We refer readers to section XI.A.5. of this final rule for an estimate of burden related to the COVID–19 Vaccination Coverage among HCP measure. The data sources for the number of HCP who have received COVID–19 vaccines may include HCP health records and paper and/or electronic documentation of vaccination given at the healthcare facility, pharmacy, or elsewhere. Further, HCP receiving vaccination elsewhere may provide documentation of vaccination. Additionally, the CDC has provided a number of resources including a tool called the Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel to help SNFs log and track this information.[106]

We also understand the commenter to state that the contraindications and precautions for the COVID–19 vaccine are changing as more studies are released. We would like to clarify that the contraindications have not changed. There are additional considerations around timing of the vaccine and which vaccine might be more appropriate for persons with underlying medications that are more clearly understood now. A summary of interim clinical considerations can be found at *https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf.*

Comment: We received a comment in response to the proposed adoption of the COVID–19 Vaccination Coverage among HCP measure for the SNF QRP recommending CMS assess Immunization Information Systems (IIS).

Response: We understand Immunization information systems (IIS) to be confidential, population-based, computerized databases that record immunization doses administered by participating providers to persons residing within a given geopolitical area but these systems are not standardized across all SNFs. The Department of HHS has an Immunization Information Systems Support Branch (IISSB), that facilitates the development, implementation, and acceptance of these systems, but they are overseen by the states and/or organizations who develop them. CMS proposed using the NHSN COVID–19 Modules for collecting data on the COVID–19 Vaccination Coverage among HCP across all sites of service, including SNFs.

After careful consideration of the public comments we received, we are finalizing the method of data submission for COVID–19 Vaccination Coverage among Healthcare Personnel measure as proposed.

4. Schedule for Data Submission of the COVID–19 Vaccination Coverage Among Healthcare Personnel Measure Beginning With the FY 2023 SNF QRP

As discussed in section VII.C.2. of this final rule, we proposed to adopt the COVID–19 Vaccination Coverage among HCP quality measure beginning with the FY 2023 SNF QRP. Given the time-sensitive nature of this measure in light of the PHE, we proposed an initial data submission period from October 1, 2021 through December 31, 2021. Starting in CY 2022, SNFs would be required to submit data for the entire calendar year beginning with the FY 2024 SNF QRP.

SNFs would submit data for the measure through the CDC/NHSN web-based surveillance system. SNFs would use the COVID–19 vaccination data collection module in the NHSN Long-term Care (LTC) Component to report the cumulative number of HCP eligible to work in the healthcare facility for at least 1 day during the reporting period, excluding persons with contraindications to COVID–19 vaccination (denominator) and the cumulative number of HCP eligible to work in the SNF for at least 1 day during the reporting period and who received a complete vaccination course against COVID–19 (numerator). SNFs would submit COVID–19 vaccination data through the NHSN for at least 1 week each month and the CDC would report to CMS quarterly. We invited public comment on this proposal. The following is a summary of the public comments received on the proposed Schedule for Data Submission of the COVID–19 Vaccination Coverage among Healthcare Personnel Measure beginning with the FY 2023 SNF QRP and our responses:

Comment: One commenter requested that CMS clarify when SNFs should submit vaccination data so the data reported will be consistent among all SNFs.

Response: We proposed SNFs submit vaccination data 1 week out of every month, but with the option for SNFs to choose which week to report.

Comment: We received several comments requesting that CMS consider easing the reporting frequency for the COVID–19 Vaccination Coverage among HCP measure. They stated that reporting vaccinations 1 week per month, rather than one time per quarter is burdensome. A couple of providers support quarterly reporting since the Influenza Vaccination among HCP measure uses quarterly reporting.

Response: We want to clarify that the COVID–19 Vaccination Coverage among HCP measure is reported to the CDC through the NHSN at least 1 week per month. Each quarter the CDC averages the 3 weeks of data collected over the 3 months and sends a quarterly average vaccination rate for each provider to CMS. We proposed a reporting schedule of 1 week per month to provide vaccination coverage data on a more timely basis than the Influenza Vaccination Coverage among HCP (NQF #0431), while also reducing the burden on SNFs that weekly reporting of this information would have been.

Comment: A commenter stated that CMS did not explain the feedback reports and the timeline for feedback on the COVID–19 Vaccination Coverage among HCP measure as required by the IMPACT Act.

Response: Historically, we have provided the following types of confidential provider feedback reports that give providers opportunity to review and correct data: (1) Review and Correct, which allows providers to review and correct their data for any given CY quarter, as early as one day following the end of the given quarter, but prior to the data submission deadline for that quarter, which falls approximately 4.5 months after the end of the quarter; and (2) Provider Preview Report, the purpose of which is to allow providers to preview their quality measure scores that will be publicly posted for the upcoming refresh of Care Compare, and also allows providers to request a formal review of the data contained within, should the provider disagree with the reported measure results.

We also provide Quality Measure Reports (Facility and Patient-Level), the purpose of which is to allow providers to improve quality based on the most up-to-date data they have entered and/or modified within our systems. This report type is not related to public reporting, and is produced solely for the benefit of quality improvement. Quality Measure Reports are not related to public reporting and do not observe the quarterly data submission deadlines of assessment-based data, and will continue to capture and include any and all data entered and/or modified beyond any data submission deadline. We

[106] Data Tracking Worksheet for COVID–19 Vaccination among Healthcare Personnel at *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.*

provide Quality Measure Reports in order to give providers, including SNFs, the most accurate picture of quality within their facility, allowing for the improvement of quality. While we have historically added new measures to the Quality Measure reports prior to public reporting, the Quality Measure reports are not related to public reporting. Because we believe it is in the best interest of Medicare beneficiaries that we publicly report the results of the COVID–19 Vaccination HCP measures as soon as is feasible, in this instance, we are not able to add this measure to the Quality Measure reports prior to public reporting. Instead, we plan to add this new measure to the Quality Measure reports in fall 2022, at the earliest, which will in no way affect a SNF's ability to review and/or correct their data for this measure, nor will it affect a SNF's ability to preview the COVID–19 Vaccination HCP data prior to the public posting of this data.

The COVID–19 Vaccination HCP measure is stewarded by the CDC NHSN. To date, we have never added any of the CDC NHSN measures to the Review and Correct report, as the data for these measures are at the CDC. In lieu of this, the CDC makes accessible to PAC providers, including SNFs, reports that are similar to the Review and Correct reports that allow for real-time review of data submissions for all CDC NHSN measures adopted for use in the CMS PAC QRPs, including the SNF QRP. These reports are referred to as the ''CMS Reports'' within the Analysis Reports page in the NHSN Application. Such a report exists for each CDC/NHSN measure within each of the PAC programs, and each report is intended to mimic the data that will be sent to CMS on their behalf. This report will exist to serve the same ''review and correct'' purposes for the COVID–19 Vaccination Coverage among HCP measure. The CDC publishes reference guides for each facility type (including SNF) and each NHSN measure, which explain how to run and interpret the reports.

We will provide SNFs with a preview of SNF performance on the COVID–19 Vaccination Coverage among HCP measure, available on the SNF Provider Preview Report, which will be issued approximately 3 months prior to displaying the measure on Care Compare. As always, SNFs will have a full 30 days to preview their data. Should a SNF disagree with their measure results, they can request a formal review of their data by CMS. Instruction for submitting such a request are available on the SNF Quality Reporting Public Reporting website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Public-Reporting.*

After careful consideration of the public comments we received, we are finalizing the schedule for data submission of the COVID–19 Vaccination Coverage among Healthcare Personnel measure beginning with the FY 2023 SNF QRP as proposed.

5. Consolidated Appropriations Act and the SNF QRP

On December 27, 2020, Congress enacted the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260). Section 111(a)(3) of Division CC of the CAA amends section 1888 of the Act by adding a new paragraph (h)(12), which requires the Secretary to apply a process to validate the measures submitted under the SNF VBP and the measures and data submitted under the SNF QRP as appropriate, which may be similar to the process specified under the Hospital Inpatient Quality Reporting (IQR) Program for validating inpatient hospital measures. We plan to develop a process for validating the SNF QRP measures and data and implement this policy as soon as technically feasible. We will provide more details and seek public comment in future rulemaking. For more information on the SNF VBP please refer to section VIII. of this rule.

H. Policies Regarding Public Display of Measure Data for the SNF QRP

1. Background

Section 1899B(g) of the Act requires the Secretary to establish procedures for making the SNF QRP data available to the public, including the performance of individual SNFs, after ensuring that SNFs have the opportunity to review their data prior to public display. SNF QRP measure data are currently displayed on the *Nursing homes including rehab services* website within Care Compare and the Provider Data Catalog. Both Care Compare and the Provider Data Catalog replaced Nursing Home Compare and *Data.Medicare.gov,* which were retired in December 2020. For a more detailed discussion about our policies regarding public display of SNF QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 SNF PPS final rule (81 FR 52045 through 52048).

2. Public Reporting of the Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization Measure Beginning With the FY 2023 SNF QRP

We proposed public reporting for the SNF HAI measure beginning with the April 2022 Care Compare refresh or as soon as technically feasible using data collected from discharges in FY 2019 beginning October 1, 2018 through September 30, 2019. Provider preview reports would be distributed in January 2022. A SNF's HAI rates would be displayed based on 1 fiscal year of data. Since we cannot publicly report data from Q1 and Q2 of 2020 due to the PHE, we proposed to use data collected from discharges in FY 2021 (October 1, 2020 through September 30, 2021) for public reporting of the SNF HAI measure in the October 2022 Care Compare refresh. Thereafter, the SNF HAI measure would be calculated using four quarters of FY data for the annual refresh on Care Compare. Claims-based measures are only refreshed on Care Compare annually. To ensure statistical reliability of the data, we proposed assigning SNFs with fewer than 25 eligible stays during a performance period to a separate category: ''The number of resident stays is too small to report.'' Eligible stays meet the measure's denominator inclusion criteria, and we refer readers to the Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program Technical Report available at *https://www.cms.gov/files/document/snf-hai-technical-report.pdf/* for more details. If a SNF had fewer than 25 eligible stays, the SNF's performance would not be publicly reported for the measure for that performance period. We refer readers to CMS's SNF QRP Public Reporting web page for more information available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Public-Reporting.*

We invited public comment on this proposal for the public display of the SNF HAI measure on Care Compare. The following is a summary of the public comments received on our proposal for the public display of the SNF HAI measure on Care Compare and our responses:

Comment: Several commenters supported the proposed public reporting schedule.

Response: We appreciate our commenters for their support in the

public display schedule of the SNF HAI measure.

Comment: A couple of commenters recommended delaying SNF HAI measure adoption due to concerns that FY 2021 will include COVID–19 data and therefore not be comparable to FY 2019 non-COVID–19 data. Commenters suggested delaying public reporting until after the end of the PHE to avoid penalizing SNFs.

Response: As long as SNFs report their HAI rates, which will occur at no additional burden since the measure is claims-based, they will satisfy the reporting requirements for the measure. To clarify, we do not intend to use FY 2019 data as a benchmark for comparison against FY 2021 data. Instead, the measure identifies SNFs that have notably higher rates of HAIs that are acquired during SNF care and result in hospitalization, when compared to the performance of other SNFs in the United States in the same time period. COVID–19 has heightened the importance of infection prevention and control programs and the need to report HAI data. Evidence suggests that higher COVID–19 transmission in healthcare settings, including SNFs, is associated with poorer infection control, staff rotations between multiple SNFs, and inadequate patient COVID–19 screenings.[107] [108] We will continue to evaluate the impact of the PHE and explore the impact of COVID–19 on quality reporting.

Comment: One commenter opposed CMS excluding SNFs with fewer than 25 admissions from public reporting of the SNF HAI measure.

Response: Infection control in small SNFs is as essential as in larger SNFs. We proposed the minimum reporting threshold to ensure sufficient reliability and to mitigate the risk of exposing personally identifiable information (PII) and protected health information (PHI). This proposal of minimum threshold for public reporting is in alignment with the existing SNF QRP claims-based measures, specifically the Discharge to Community (DTC) and Potentially Preventable 30-Day Post-Discharge Readmission (PPR) measures.

After careful consideration of the public comments we received, we are finalizing the proposal to publicly report the SNF HAI measure beginning with the April 2022 refresh as proposed.

3. Public Reporting of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2023 SNF QRP

We proposed to publicly report the COVID–19 Vaccination Coverage among Healthcare Personnel measure beginning with the October 2022 Care Compare refresh or as soon as technically feasible using data collected for Q4 2021 (October 1, 2021 through December 31, 2021). If finalized as proposed, a SNF's HCP COVID–19 vaccination coverage rate would be displayed based on one quarter of data. Provider preview reports would be distributed in July 2022. Thereafter, HCP COVID–19 vaccination coverage rates would be displayed based on one quarter of data updated quarterly. Subsequent to this, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four full quarters of data is reached. Thereafter, the measure would be reported using four rolling quarters of data.

We invited public comment on this proposal for the public display of the COVID–19 Vaccination Coverage among HCP measure on Care Compare. The following is a summary of the public comments received on our proposal for the public display of the COVID–19 Vaccination Coverage among HCP measure on Care Compare and our responses:

Comment: Several commenters supported the proposal to publicly report the COVID–19 Vaccination Coverage among HCP measure beginning with the October 2022 Care Compare refresh or as soon as technically feasible. The commenters stated that publishing facility-level data on HCP vaccination rates would also provide additional information about SNFs pandemic response and readiness efforts.

Response: We thank the commenters for their support and agree that publishing facility-level data on HCP vaccination rates would also provide additional information about SNFs' pandemic response and readiness efforts.

Comment: One commenter suggested reporting the percentage of HCP that had received their dose, broken out by first and second dose, as well as the percentage of all facility staff that have received their dose, broken out by first and second dose.

Response: We believe the value of the measure is in knowing the number of HCP who have completed their vaccination course as accumulating evidence indicates fully vaccinated people are able to participate in most activities with very low risk of acquiring or transmitting SARS–CoV–2.[109]

Comment: A commenter requested that CMS reconsider how the measure is calculated for public reporting. They supported the concept of reporting one quarter of data. They recommend that after the first refresh, rather than calculating a summary measure of the COVID–19 vaccination coverage from the 3 monthly modules of data reported for the quarter during each refresh and adding one additional quarter of data to the measure calculation during each advancing refresh, until the point that four full quarters of data is reached, to use an alternate approach. They recommend updating the information monthly with only the most recent data, such that the measure would be consumed as the most recent quarter of data refreshed quarterly. They caution that averaging over 12 months would result in the dilution of the most recent, and potentially more meaningful information, and may actually discourage higher provider vaccine uptake rates since it would be harder to change performance on this measure.

Response: We agree with the commenters' concern with regard to timely display of publicly reported data. We believe it is important to make the most up-to-date data available to beneficiaries, which will support them in making essential decisions about health care. We agree with these concerns, and find that it is appropriate to revise the public reporting policy for this measure to use quarterly reporting, as opposed to averaging over four rolling quarters, which allows the most recent quarter data to be displayed for the reasons outlined by the commenter. This revision would result in publishing information that is more up to date and would not affect the data collection schedule established for submitting data to NHSN for the COVID–19 vaccination

[107] Kimball, A., Hatfield, K.M., Arons, M., James, A., Taylor, J., Spicer, K., Bardossy, A.C., Oakley, L.P., Tanwar, S., Chisty, Z., Bell, J.M., Methner, M., Harney, J., Jacobs, J.R., Carlson, C.M., McLaughlin, H.P., Stone, N., Clark, S., Brostrom-Smith, C., Page, L.C., . . . CDC COVID–19 Investigation Team (2020). Asymptomatic and Presymptomatic SARS–CoV–2 Infections in Residents of a Long-Term Care Skilled Nursing Facility—King County, Washington, March 2020. MMWR. Morbidity and mortality weekly report, 69(13), 377–381. *https://doi.org/10.15585/mmwr.mm6913e1.*

[108] McMichael, T.M., Clark, S., Pogosjans, S., Kay, M., Lewis, J., Baer, A., Kawakami, V., Lukoff, M.D., Ferro, J., Brostrom-Smith, C., Riedo, F.X., Russell, D., Hiatt, B., Montgomery, P., Rao, A.K., Currie, D.W., Chow, E.J., Tobolowsky, F., Bardossy, A.C., Oakley, L.P., . . . Public Health—Seattle & King County, EvergreenHealth, and CDC COVID–19 Investigation Team (2020). COVID–19 in a Long-Term Care Facility—King County, Washington, February 27–March 9, 2020. MMWR. Morbidity and mortality weekly report, 69(12), 339–342. *https://doi.org/10.15585/mmwr.mm6912e1.*

[109] Centers for Disease Control and Prevention. Science Brief: COVID–19 Vaccines and Vaccination. Available at *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html.*

measure. This revision would simply update the way the measure's data are displayed for the public reporting purposes.

Comment: One commenter recommended that CMS either delay adoption of the measure for at least 1 year (that is, until October 1, 2022), or adopt the measure for voluntary reporting for at least the first year so it would not appear as though the Administration supported mandatory vaccinations.

Response: We believe that the unprecedented risks associated with the COVID–19 PHE warrant direct and prompt attention and, that it is important to begin publicly reporting this measure as proposed. However, as discussed in section VII.C.2.e. of this final rule, the COVID–19 Vaccination Coverage among HCP measure does not require SNF HCP to be vaccinated in order for SNFs to report the measure under the SNF QRP.

Comment: One commenter stated that several state legislatures were considering laws to prohibit an employer from forcing employees to be vaccinated for COVID–19, while other states are considering legislation to specifically authorize employer-mandated vaccinations. The commenter is concerned that provider performance on the measure could vary significantly based on differing state laws.

Response: We believe that the unprecedented risks associated with the PHE for COVID–19 warrant direct attention. Further, the COVID–19 Vaccination Coverage among HCP measure does not require providers to adopt mandatory vaccination policies. To support a comprehensive vaccine administration strategy, we encourage SNFs to engage in the provision of appropriate and accessible education and vaccine-offering activities. Many SNFs across the country are educating staff, patients, and patient representatives, participating in vaccine distribution programs, and reporting vaccine administration. The CDC has a number of resources [110] available to providers to assist in building vaccine confidence.

Consistent vaccination reporting by SNFs via the NHSN will help patients and their caregivers identify SNFs that have potential issues with vaccine confidence or slow uptake among staff. Implementation of COVID–19 vaccine education and vaccination programs in SNFs will help protect patients and staff, allowing for an expedited return to more normal routines, including timely preventive healthcare; family, caregiver, and community visitation; and group and individual activities.[111]

Comment: Several commenters questioned whether the COVID–19 Vaccination Coverage among HCP measure's information will be of value in 2023 and beyond given the time associated with data collection, submission, and validation. While they support the rights of consumers to access real-time meaningful data to help inform healthcare decision-making, they believe that the use of a single, dated measure is not a true reflection of the safety or quality of care delivered at the SNF.

Response: We disagree with the commenter and believe the measure should be publicly reported. As far as the timeliness of the reporting, the SNF QRP public display policies, as finalized in the FY 2017 SNF PPS final rule (81 FR 52041), allows 4.5 months after the end of the reporting quarter for SNFs to submit SNF QRP data. A number of administrative tasks must then occur in sequential order between the time SNF QRP data are submitted and are reported in Care Compare to ensure the validity of the data and to allow SNFs sufficient time to appeal any determinations of APU non-compliance. We have streamlined the process as much as possible, but must take these steps to ensure we are publishing accurate data. Additionally, the COVID–19 Vaccination Coverage among HCP measure will be one of several measures on Care Compare that patients and caregivers can use to make informed healthcare decisions. As with all other measures, we will routinely monitor this measure's performance, including assessing performance gaps across SNFs, and ensure the measure remains valid, reliable, and useful to consumers.

Comment: One commenter stated that since the COVID–19 vaccination rates for both staff and residents are now posted on the nursing home site at *data.cms.gov* (as a result of the new reporting requirements at § 483.80(g)) that adding the COVID–19 Vaccination Coverage among HCP measure to the SNF QRP for the stated purpose of transparency appears to be duplicative, unnecessary, and potentially more confusing. One commenter urged the CDC and CMS to use the data collected as a result of the change made to LTC Requirements of Participation at § 483.80(g) to publish on Care Compare since they believe it would provide a more accurate and comprehensive measure of HCP vaccination. Another commenter urged CMS to direct consumers to use the TeleTracking system to find vaccination rates.

Response: We disagree with these comments. The Care Compare provides a user-friendly interface that patients and caregivers can use to make informed decisions about healthcare based on cost, quality of care, volume of services, and other data, while also giving them the option to compare SNFs using this information. The data found on *data.cms.gov* and in the TeleTracking system do not have these features.

Comment: Another commenter questioned whether incorporating 2021 vaccination rates for HCP into quality ratings on Medicare Compare in 2023 would provide valuable information to SNF residents and their families.

Response: We are interpreting the commenter's question to be about the COVID–19 Vaccination Coverage among HCP measure and the timeline for reporting it on Care Compare. We proposed to report the inaugural COVID–19 Vaccination Coverage among HCP measure beginning with the October 2022 Care Compare refresh or as soon as technically feasible using data collected for Q4 2021 (October 1, 2021 through December 31, 2021). If finalized as proposed, provider preview reports would be distributed in July 2022.

Comment: A commenter did not support the proposal to use a shortened reporting timeframe of October 2021–December 2021 to meet the APU reporting requirements for FY 2023.

Response: We interpret the commenter to be referring to the SNF QRP reporting requirements to meet the compliance threshold for the FY 2023 Annual Payment Update. Our proposal to use of one quarter of data for the initial year of quality reporting for a new measure is consistent with the approach finalized in the FY 2016 SNF PPS final rule (80 FR 46389 to 46777) for all new measures in their first year of data reporting.

Comment: Commenters had differing opinions on whether the information obtained from the COVID–19 Vaccination Coverage among HCP measure would be helpful to consumers. Some stated that it does little to guide patients and their caregivers in the discharge planning process or to distinguish SNFs from one another. Another commenter acknowledged the value of this information for public

[110] Centers for Disease Control and Prevention. Building Confidence in COVID–19 Vaccines. Available at *https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html.*

[111] Centers for Disease Control and Prevention. Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID–19 Vaccination. Available at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html.* Accessed June 26, 2021.

health and educational purposes, but still believes it would not be appropriate at this time to report publicly on MUC20–044 for the purposes of assessing SNF quality performance.

Response: We interpret the commenter to be referring to the CMS 2020 Measures Under Consideration (MUC) list and specifically the SARS–CoV–2 Vaccination Coverage among HCP measure (MUC20–044), whose name was subsequently changed to the COVID–19 Vaccination Coverage among HCP measure. This measure is important at this time because, as illustrated in Medicare claims and encounter data, the number of Medicare beneficiaries diagnosed with COVID–19 exceeded 4.3 million as of April 24, 2021.[112] We believe that the toll the COVID–19 pandemic has taken on Medicare beneficiaries, including SNF residents, demonstrates the need for increased action to mitigate the effects of the ongoing pandemic. Additionally, public reporting of this measure will inform patients and families of more recent information on quality of care provided in SNFs so patients and caregivers are able to make informed choices about critical dimensions of quality.

After careful consideration of the public comments we received, we are finalizing our proposal to publicly report the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the October 2022 Care Compare refresh or as soon as technically feasible using data collected for Q4 2021 (October 1, 2021 through December 31, 2021). However, based on public comment, we will not finalize our plan to add one additional quarter of data during each advancing refresh, until the point that four full quarters of data is reached and then report the measure using four rolling quarters of data. We will instead only report the most recent quarter of data. This revision would result in publishing more meaningful information that is up to date.

4. Public Reporting of Quality Measures in the SNF QRP With Fewer Quarters Due to COVID–19 Public Health Emergency (PHE) Exemptions

a. COVID–19 Public Health Emergency Temporary Exemptions

Under the authority of section 319 of the Public Health Service Act, the Secretary of Health and Human Services declared a public health emergency (PHE) effective as of January 27, 2020. On March 13, 2020, subsequent to a presidential declaration of national emergency under the Stafford Act, the Secretary invoked section 1135(b) of the Act (42 U.S.C. 1320b–5) to waive or modify the requirements of titles XVIII, XIX, and XXI of the Act and regulations related to the PHE for COVID–19, effective as of March 1, 2020.[113] On March 27, 2020, we sent a guidance memorandum under the subject title, ''Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19'' to the Medicare Learning Network (MLN) Connects Newsletter and Other Program-Specific Listserv Recipients,[114] hereafter referred to as the March 27, 2020 CMS Guidance Memo. In that memo we granted an exception to the SNF QRP reporting requirements from Q4 2019 (October 1, 2019 through December 31, 2019), Q1 2020 (January 1, 2020 through March 31, 2020), and Q2 2020 (April 1, 2020 through June 30, 2020). We also stated that we would not publicly report any SNF QRP data that might be greatly impacted by the exceptions from Q1 and Q2 of 2020. This exception impacted the schedule for public reporting that would have included those two quarters of data.

SNF quality measures are publicly reported on Care Compare. Care Compare uses four quarters of data for MDS assessment-based measures and eight quarters for claims-based measures. Table 26 displays the original schedule for public reporting of SNF QRP measures.[115]

[112] Medicare COVID–19 Data Snapshot Overview. Available at *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.* Accessed July 12, 2021.

[113] *https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.*

[114] *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

[115] More information about the SNF QRP Public Reporting schedule can be found on the SNF QRP Public Reporting website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Public-Reporting.*

TABLE 26: SNF Quarters in Care Compare Original Schedule for Refreshes Affected by COVID-19 PEH Exemptions - Assessment and Claims Based Measures

Quarter Refresh	SNF Quarters in Original Schedule for Care Compare
January 2021	MDS: Q2 2019 – Q1 2020 (4 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
April 2021	MDS: Q3 2019 – Q2 2020 (4 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
July 2021	MDS: Q4 2019 – Q3 2020 (4 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
October 2021	MDS: Q1 2020 – Q4 2020 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
January 2022	MDS: Q2 2020 – Q1 2021 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
April 2022	MDS: Q3 2020 – Q2 2021 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
July 2022	MDS: Q4 2020 – Q3 2021 (4 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
October 2022	MDS: Q1 2021 – Q4 2021 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
January 2023	MDS: Q2 2021 – Q1 2022 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
April 2023	MDS: Q3 2021 – Q2 2022 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
July 2023	MDS: Q4 2021 – Q3 2022 (4 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)

During 2020, we conducted testing to inform decisions about publicly reporting data for those refreshes which include partially and/or fully exempt data (discussed below). The testing helped us develop a plan for posting data that are as up-to-date as possible and that also meet acceptable standards for public reporting. We believe that the plan allows us to provide consumers with helpful information on the quality of SNF care, while also making the necessary adjustments to accommodate the exemption provided SNFs. The following sections provide the results of our testing, and explain how we used the results to develop plans for accommodating exempt and partially-exempt data in public reporting.

b. Exempted Quarters

In the March 27, 2020 Medicare Learning Network (MLN) Newsletter on Exceptions and Extensions for Quality Reporting Program (QRP) Requirements, we stated that we would not report any PAC quality data that might be greatly impacted by the exemptions granted for Quarter 1 and Quarter 2 of 2020. Given the timing of the PHE onset, we determined that we would not use SNF MDS assessments or SNF claims from Quarter 1 and Quarter 2 of 2020 for public reporting, but that we would assess the COVID–19 PHE impact on data from Quarter 4 2019. Before proceeding with the October 2020 refresh, we conducted testing to ensure that, despite the voluntary nature of reporting for that quarter, public reporting would still meet our public reporting standards. We found the level of reporting, measured in the number of eligible stays and providers, and the reported outcomes, to be in line with levels and trends observed in FY 2018 and FY 2019. We note that Quarter 4 2019 ended before the onset of the COVID–19 pandemic in the United States. Thus, we proceeded with including these data in SNF QRP measure calculations for the October 2020 refresh.

c. Update on Data Freeze and Proposal for January 2022 Public Reporting Methodology for SNF Claims-Based and MDS Assessment-Based Measures

In addition to the January 2021 refresh, there are several other forthcoming refreshes for which the original public reporting schedules included exempted quarters of SNF QRP data. The impacted refreshes for MDS assessment and claims based measures are outlined in (Table 26). We determined that freezing the data displayed on the website with the October 2020 refresh values—that is, hold data constant after the October 2020 refresh data on the website without subsequent update—would be the most straightforward, efficient, and equitable approach for SNFs. Thus, we decided that, for as many refreshes as necessary, we would hold data constant on the website with the October 2020 data, and communicate this decision to the public.

Because October 2020 refresh data will become increasingly out-of-date and thus less useful for consumers, we analyzed whether it would be possible to use fewer quarters of data for one or more refreshes and thus reduce the number of refreshes that continue to display October 2020 data. Using fewer quarters of more up-to-date data requires that (1) a sufficient percentage of SNFs would still likely have enough assessment data to report quality measures (reportability); and (2) fewer quarters would likely produce similar measure scores for providers, with similar reliability, and thus not unfairly represent the quality of care SNFs provide during the period reported in a given refresh (reliability).

To assess these criteria, we conducted reportability and reliability analysis using 3 quarters of data in a refresh, instead of the standard 4 quarters of data for reporting assessment-based measures and using 6 quarters instead of 8 for claims-based measures. Specifically, we used historical data to calculate MDS assessment based and SNF claims based quality measures under two scenarios:

1. *Standard Public Reporting (SPR) Base Scenario:* We used four quarters of CY 2019 data as a proxy alternative for the exempted quarters in CY 2020 in order to compare results. For assessment-based measures, the quarters used in this scenario are Q1 through Q4 2019. For claims-based measures, the quarters used in this scenario are Q1 2018 through Q4 2019.

2. *COVID–19 Affected Reporting (CAR) Scenario:* We calculated SNF QRP measures using 3 quarters (Q2 2019 through Q4 2019) of SNF QRP data for assessment-based measures, and 6 quarters (Q1 2018 through Q4 2018 and Q3 2019 through Q4 2019) for claims-based measures. The CAR scenario uses the most recently available data to simulate the public health emergency reality where quarters 1 and 2 of a calendar year must be excluded from calculation. Quarterly trends in MDS assessment-based and claims based measures indicate that these measures do not exhibit substantial seasonal variation.

To assess performance in these scenarios, we calculated the reportability as the percent of SNFs meeting the case minimum for public reporting (the public reporting threshold). To test the reliability of restricting the SNFs included in the SPR Base Scenario to those included in the CAR Scenario, we performed three tests on the set of SNFs included in both scenarios. First, we evaluated measure correlation using the Pearson and Spearman correlation coefficients, which assess the alignment of SNFs' provider scores. Second, for each scenario, we conducted a split-half reliability analysis and estimated intraclass correlation (ICC) scores, where higher scores imply better internal reliability. Modest differences in ICC scores between both scenarios would suggest that using fewer quarters of data does not impact the internal reliability of the results. Third, we estimated reliability scores where a higher value indicates that measure scores are relatively consistent for patients admitted to the same SNF and variation in the measure reflects true differences across providers. To calculate the reliability results, we restricted the SNFs included in the SPR scenario to those included in the CAR scenario.

Our testing indicated that the expected impact of using fewer quarters of data on reportability and reliability of MDS assessment-based and claims based measures is acceptable.

We proposed to use the CAR scenario as the approach for the following affected refreshes for MDS assessment-based measures, the affected refresh is the January 2022 refresh; for claims-based measures, the affected refreshes occur from January 2022 through July 2023. For the earlier four affected refreshes (January, April, July, and October 2021), we decided to hold constant the Care Compare website with October 2020 data. We communicated this decision in a Public Reporting Tip Sheet, which is located at *https://www.cms.gov/files/document/snfqrp-covid19prtipsheet-october2020.pdf.*

Our proposal of the CAR approach for the affected refreshes would allow us to begin displaying more recent data in January 2022, rather than continue displaying October 2020 data (Q1 2019 through Q4 2019 for assessment-based measures, Q4 2017 through Q3 2019 for claims-based measures). We believe that resuming public reporting starting in January 2022 with fewer quarters of data can assist consumers by providing more recent quality data as well as more actionable data for SNF providers. Our testing results indicate we can achieve these positive impacts with acceptable changes in reportability and reliability. Table 27 summarizes the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for assessment-based measures. Tables 28 and 29 summarize the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for claims-based measures.

We invited public comment on the proposal to use the CAR scenario to publicly report SNF measures for the January 2022 through July 2023 refreshes.

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TABLE 27: Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for SNF MDS Assessment-based QMs

Quarter Refresh	MDS Assessment Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
October 2020	Q1 2019 – Q4 2019 (4)
January 2021	Q1 2019 – Q4 2019 (4)
April 2021	Q1 2019 – Q4 2019 (4)
July 2021	Q1 2019 – Q4 2019 (4)
October 2021	Q1 2019 – Q4 2019 (4)
January 2022	Q3 2020 – Q1 2021 (3)
April 2022	Q3 2020 – Q2 2021 (4)* *Normal reporting resumes with 4 quarters of data

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

TABLE 28: Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for SNF Claims-based QMs

Quarter Refresh	Claims-based Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
October 2020	Q4 2017 – Q3 2019 (8)
January 2021	Q4 2017 – Q3 2019 (8)
April 2021	Q4 2017 – Q3 2019 (8)
July 2021	Q4 2017 – Q3 2019 (8)
October 2021	Q4 2017 – Q3 2019 (8)
January 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
April 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
July 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
October 2022	Q4 2019, Q3 2020 – Q3 2021 (6)
January 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
April 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
July 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
October 2023	Q4 2020 – Q3 2022 (8)* *Normal reporting resumes with 8 quarters of data

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

TABLE 29: Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for the SNF HAI Measure

Quarter Refresh	Claims-based Quarters in Proposed Schedule for Care Compare (number of quarters)
April 2022	Q4 2018 – Q3 2019 (4)
July 2022	Q4 2018 – Q3 2019 (4)
October 2022	Q4 2020 - Q3 2021 (4) *Normal reporting resumes for claims-based measures refreshed annually

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The following is a summary of the public comments received on the proposal to use the CAR scenario to publicly report SNF measures for the January 22 through July 2023 refreshes and our responses:

Comment: We received two comments on the proposed COVID–19 Affected Reporting (CAR) scenario methodology. One commenter supported the proposal to report fewer quarters of data. Another commenter stated that the CAR scenario appeared to adequately ensure data reportability and reliability and requested that CMS continue to monitor modified Care Compare refreshes until normal reporting resumes to ensure the CAR approach produces valid and reliable results.

Response: We thank the commenters for their support and will continue to monitor measures to identify any concerning trends as part of our routine monitoring activities to regularly assess measure performance, reliability, and reportability for all data submitted for the SNF QRP.

Comment: Most commenters expressed their appreciation for the flexibility that CMS offered to SNF providers during the early months of the COVID–19 pandemic in granting an exception to the SNF QRP reporting requirements from Q1 2020 (January 1, 2020 through March 31, 2020) and Q2 2020 (April 1, 2020 through June 30, 2020). However, a number of commenters raised concerns with CMS' proposal to utilize fewer than the standard number of quarters for public reporting of quality measures on Care Compare, since it includes SNF QRP reporting from Q3 2020 (July 1, 2020 through September 30, 2020) and Q4 2020 (October 1, 2020 through December 31, 2020). Commenters pointed out that the COVID–19 pandemic community infection rate surged repeatedly across different regions of the country, at different times, and did not begin to become under control until Q1 2021 after the first wave of COVID–19 vaccine was disseminated to SNF residents and staff. Instead, they urged CMS to exclude the entire calendar year 2020 data.

Response: While we understand that there are concerns related to the use of Q3 and Q4 2020 data, we believe that the value of the information provided to users through public reporting outweighs these concerns. Additionally, we provided a 6-month exception to

SNF QRP reporting requirements related to the PHE, and we believe that timeframe was sufficient for providers to adjust to the change in care patterns associated with the pandemic. We further believe that the public display of quality data is extremely important so patients and caregivers can continue to make informed healthcare choices. The continued need for access to provider quality data on Care Compare by CMS beneficiaries outweighs any potential provider impacts.

As described above, we conducted testing to inform our decisions about publicly reporting data for refreshes using Q3 and Q4 2020. As discussed in section VI.H.4.c. of the FY 2021 SNF PPS proposed rule (86 FR 20004 through 20005), the testing helped us develop a plan that we believe meets acceptable standards for public reporting. SNFs that believe they were disproportionately affected by the PHE may apply for an individual exception or extension related to the SNF QRP reporting requirements for Q3 and/or Q4 2020. Instructions for requesting an extraordinary circumstances exemption (ECE) may be found on the SNF QRP Reconsideration and Exception and Extension web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-QR-Reconsideration-and-Exception-and-Extension.*

Comment: One commenter believes public reporting should be frozen until the first quarter after the end of the PHE. Since the proposed public reporting schedule would utilize data submitted while the country was still under a PHE, particularly during the proposed Q3 2020 through Q1 2021 timeframes, they believe it may not reflect normal SNF performance and results both at the facility, and geographically.

Response: We disagree with the commenter about freezing the data until after the first quarter of the end of the PHE. COVID–19 has caused us to take a number of actions to further protect SNF residents. Resuming public reporting will inform patients and families of more recent information on quality of care provided in SNFs. As we progress, we will analyze SNF QRP measures for any significant changes, and take any actions needed to continue the improvement and protection of patient health and safety.

Comment: Several commenters believe that payments to their SNFs would be negatively impacted since their state Medicaid systems use quality measure data and the star ratings published on Care Compare to determine quality incentive payment rates to nursing facilities. They urged CMS not to penalize providers under the Five-Star rating system for measure performance ratings derived during Q3 2020 through Q1 2021.

Response: We acknowledge that other programs may utilize the SNF QRP for their own purposes. We proposed the COVID–19 Vaccination Coverage among HCP measure for the SNF QRP. Comments about state Medicaid programs and the Five-Star rating system are outside the scope of this final rule.

Comment: One commenter stated that due to specific CDC and CMS mandated COVID–19 infection control requirements, specific MDS items used for some measures (that is, mobility and self-care) may have been directly and artificially impacted, which could further skew the results during this period. The inability to account for or risk-adjust the measures for the influence of a worldwide airborne viral pandemic was also given as justification for excluding additional quarters in 2020.

Response: We are uncertain what the commenter means in stating that some measures may have been artificially impacted. We acknowledge the efforts that SNFs have gone to keep their residents and staffs as safe as possible during the COVID–19 PHE. One of the reasons the SNF QRP reporting requirement waivers for reporting measure data was granted for Q4 2019 through Q2 2020 was to enable SNFs to address their residents' care, and to acclimate to care patterns associated with the PHE. However, CMS uses all SNF QRP data submitted to CMS for the purposes of public reporting. As stated previously, we routinely monitor measures to identify any concerning trends, and will continue to do so as part of our routine monitoring activities to regularly assess measure performance, reliability, and reportability for all data submitted for the SNF QRP.

Comment: One commenter requested that CMS include a notation on Care Compare to explain the temporary adjustments made for the PHE and that consumers should consider additional information when selecting facilities such as survey results and in-person facility visits.

Response: We will notify consumers of the use of fewer quarters of data reported on Care Compare when the website is refreshed. However, we do not believe that posting additional messaging alluding to how SNF measure scores may or may not be affected by the ongoing PHE would be helpful to consumers. Such messages would give the impression that the data posted on Care Compare are inaccurate or cannot be used when making informed healthcare decisions, which is not the case given the extensive testing CMS conducts.

After careful consideration of the public comments, we are finalizing the revisions to use the CAR scenario to publicly report SNF measures for the January 2022 through July 2023 refreshes as proposed.

I. Miscellaneous Comments

Comment: One commenter encouraged CMS to provide more infrastructure support for SNFs to adopt certified electronic technology to facilitate meaningful data exchange. They point out the importance of knowing whether the data have been received and acted upon, as well as the opportunity to understand just what parts of the data are most beneficial to the receiving provider.

Response: This comment is out of scope and is not relevant to our proposal to update the TOH Information measure.

VIII. Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program

A. Statutory Background

Section 215(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) authorized the SNF VBP Program (the ''Program'') by adding section 1888(h) to the Act. As a prerequisite to implementing the SNF VBP Program, in the FY 2016 SNF PPS final rule (80 FR 46409 through 46426), we adopted an all-cause, all-condition hospital readmission measure, as required by section 1888(g)(1) of the Act, and discussed other policies to implement the Program such as performance standards, the performance period and baseline period, and scoring. SNF VBP Program policies have been codified in our regulations at 42 CFR 413.338. For additional background information on the SNF VBP Program, including an overview of the SNF VBP Report to Congress and a summary of the Program's statutory requirements, we refer readers to the following prior final rules:

- In the FY 2017 SNF PPS final rule (81 FR 51986 through 52009), we adopted an all-condition, risk-adjusted potentially preventable hospital readmission measure for SNFs, as required by section 1888(g)(2) of the Act, adopted policies on performance standards, performance scoring, and sought comment on an exchange

function methodology to translate SNF performance scores into value-based incentive payments, among other topics.

- In the FY 2018 SNF PPS final rule (82 FR 36608 through 36623), we adopted additional policies for the Program, including an exchange function methodology for disbursing value-based incentive payments.
- In the FY 2019 SNF PPS final rule (83 FR 39272 through 39282), we adopted more policies for the Program, including a scoring adjustment for low-volume facilities.
- In the FY 2020 SNF PPS final rule (84 FR 38820 through 38825), we adopted additional policies for the Program, including a change to our public reporting policy and an update to the deadline for the Phase One Review and Correction process. We also adopted a data suppression policy for low-volume SNFs.
- In the FY 2021 SNF PPS final rule (85 FR 47624 through 47627), we amended regulatory text definitions at § 413.338(a)(9) and (11) to reflect the definition of Performance Standards and the updated Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure name, respectively. We also updated the Phase One Review and Correction deadline and codified that update at § 413.338(e)(1). Additionally, we codified the data suppression policy for low-volume SNFs at § 413.338(e)(3)(i), (ii), and (iii) and amended § 413.338(e)(3) to reflect that SNF performance information will be publicly reported on the Nursing Home Compare website and/or successor website (84 FR 38823 through 38824) which since December 2020 is the Provider Data Catalogue website (*https://data.cms.gov/provider-data/*).

The SNF VBP Program applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. Section 1888(h)(1)(B) of the Act requires that the SNF VBP Program apply to payments for services furnished on or after October 1, 2018. We believe the implementation of the SNF VBP Program is an important step towards transforming how payment is made for care, moving increasingly towards rewarding better value, outcomes, and innovations instead of merely rewarding volume.

B. SNF VBP Program Measures

For background on the measures we have adopted for the SNF VBP Program, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46419), where we finalized the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) that we are currently using for the SNF VBP Program. We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51987 through 51995), where we finalized the Skilled Nursing Facility 30-Day Potentially Preventable Readmission Measure (SNFPPR) that we will use for the SNF VBP Program instead of the SNFRM as soon as practicable, as required by statute. The SNFPPR measure's name is now ''Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure'' (§ 413.338(a)(11)). We intend to submit the SNFPPR measure for NQF endorsement review during the Fall 2021 cycle, and to assess transition timing of the SNFPPR measure to the SNF VBP Program after NQF endorsement review is complete.

1. Flexibilities for the SNF VBP Program in Response to the Public Health Emergency Due to COVID–19

In previous rules, we have identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating facilities' or practitioners' control. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors.

A significant example of the type of external factor that may affect quality measurement is the COVID–19 public health emergency (PHE), which has had, and continues to have, significant and ongoing effects on the provision of medical care in the country and around the world. The COVID–19 pandemic and associated PHE has impeded effective quality measurement in many ways. Changes to clinical practices to incorporate safety protocols for medical personnel and patients, as well as unpredicted changes in the number of stays and facility-level case mixes, have affected the data that SNFs report under the SNF VBP Program and the resulting measure calculations. CMS is considering whether the SNF readmission measure specifications should be updated to account for changes in SNF admission and/or hospital readmission patterns that we have observed during the PHE. Additionally, because COVID–19 prevalence is not identical across the country, facilities located in different areas have been affected differently at different times throughout the pandemic. Under those circumstances, we remain concerned that the SNF readmission measure scores are distorted, which would result in skewed payment incentives and inequitable payments, particularly for SNFs that have treated more COVID–19 patients than others.

It is not our intention to penalize SNFs based on measure scores that we believe are distorted by the COVID–19 pandemic, and are thus not reflective of the quality of care that the measure in the SNF VBP Program was designed to assess. As discussed above, the COVID–19 pandemic has had, and continues to have, significant and enduring effects on health care systems around the world, and affects care decisions, including readmissions to the hospital as measured by the SNF VBP Program. As a result of the PHE, SNFs could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, lower incentive payments in the SNF VBP Program. Additionally, because COVID–19 prevalence has not been identical across the country, SNFs located in different regions have been affected differently during the PHE. As a result, we are concerned that regional differences in COVID–19 prevalence during the revised performance period for the FY 2022 SNF VBP Program, which includes one quarter of data during the pandemic (July 1, 2020 through September 30, 2020), have directly affected SNF readmission measure scores for the FY 2022 SNF VBP Program Year. Although these regional differences in COVID–19 prevalence rates do not reflect differences in the quality of care furnished by SNFs, they directly affect the value-based incentive payments that these SNFs are eligible to receive and could result in an unfair and inequitable distribution of those incentives. These inequities could be especially pronounced for SNFs that have treated a large number of COVID–19 patients.

Therefore, we proposed to adopt a policy for the duration of the PHE for COVID–19 that would enable us to suppress the use of SNF readmission measure data for purposes of scoring and payment adjustments in the SNF VBP Program if we determine that circumstances caused by the PHE for COVID–19 have affected the measure and the resulting performance scores significantly. We proposed that under this policy, if we determine that the suppression of the SNF readmission measure is warranted for a SNF VBP Program Year, we would calculate the SNF readmission measure rates for that program year but then suppress the use of those rates to generate performance scores, rank SNFs, and generate value-based incentive payment percentages based on those performance scores. We

would instead assign each eligible SNF a performance score of zero for the program year to mitigate the effect that the distorted measure results would otherwise have on the SNF's performance score and incentive payment multiplier. We would also reduce each eligible SNF's adjusted Federal per diem rate by the applicable percent (2 percent) and then further adjust the resulting amounts by a value-based incentive payment amount equal to 60 percent of the total reduction. Those SNFs subject to the Low-Volume Adjustment policy would receive 100 percent of their 2 percent withhold in accordance with the policy previously finalized in the FY 2019 SNF PPS final rule (83 FR 39278 through 39280). We would also provide each SNF with its SNF readmission measure rate in confidential feedback reports so that the SNF is aware of the observed changes to its measure rates. We would also publicly report the FY 2022 SNF readmission measure rates with appropriate caveats noting the limitations of the data due to the PHE for COVID–19.

In developing this proposed policy, we considered what circumstances caused by the PHE for COVID–19 would affect a quality measure significantly enough to warrant its suppression in a value-based purchasing program. We believe that a significant deviation in measured performance that can be reasonably attributed to the PHE for COVID–19 is a significant indicator of changes in clinical conditions that affect quality measurement. Similarly, we believe that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the PHE. As has been the case during the COVID–19 PHE, we believe that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols, may affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also note that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new disease or conditions. Finally, we believe that, as evidenced during the COVID–19 PHE, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or facility-level case mix may result in significant distortions to quality measurement.

Based on these considerations, we developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress the SNF readmission measure for one or more program years that overlap with the PHE for COVID–19. We proposed to adopt these Measure Suppression Factors for use in the SNF VBP Program and, for consistency, the following other value-based purchasing programs: Hospital Value-Based Purchasing Program, Hospital Readmissions Reduction Program, HAC Reduction Program, and End-Stage Renal Disease Quality Incentive Program. We believe that these Measure Suppression Factors will help us evaluate the SNF readmission measure in the SNF VBP Program and that their adoption in the other value-based purchasing programs noted above will help ensure consistency in our measure evaluations across programs. The proposed Measure Suppression Factors are:

(1) Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.

(2) Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.

(3) Rapid or unprecedented changes in:

- Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
- The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

(4) Significant national shortages or rapid or unprecedented changes in:

- Healthcare personnel;
- Medical supplies, equipment, or diagnostic tools or materials; or
- Patient case volumes or facility-level case mix.

We stated in the proposed rule that we had also considered alternatives to this proposed policy that could also fulfill our objective to not hold facilities accountable for measure results that are distorted due to the PHE for COVID–19. As noted above, the country continues to grapple with the effects of the COVID–19 PHE, and in March 2020, we issued a nationwide, blanket ECE for all hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the PHE for COVID–19. This blanket ECE excepted all data reporting requirements for Q1 and Q2 2020 data. For claims-based measures, we also stated that we would exclude all qualifying Q1 and Q2 2020 claims from our measure calculations. We considered extending the blanket ECE that we issued for Q1 and Q2 2020 to also include Q3 2020 data. However, this option would result in less than 12 months of data being used to calculate the single readmissions measure in the Program for multiple program years, which we do not believe would provide an accurate assessment of the quality of care provided in SNFs. This option would also leave no comprehensive data available for us to provide confidential performance feedback to providers nor for monitoring and to inform decision-making for potential future programmatic changes, particularly as the PHE is extended.

As we stated in the proposed rule, we view this measure suppression proposal as a necessity to ensure that the SNF VBP Program does not reward or penalize facilities based on factors that the SNF readmission measure was not designed to accommodate. We also stated that we intend for this proposed policy to provide short-term relief to SNFs when we have determined that one or more of the Measure Suppression Factors warrants the suppression of the SNF readmission measure.

We invited public comments on this proposal for the adoption of a measure suppression policy for the SNF VBP Program for the duration of the PHE for COVID–19, and also on the proposed Measure Suppression Factors that we developed for purposes of this proposed policy.

We also invited comment on whether we should consider adopting a measure suppression policy that would apply in a future national PHE, and if so, whether under such a policy, we should have the flexibility to suppress quality measures without specifically proposing to do so in rulemaking. We also requested comment on whether we should in future years consider adopting any form of regional adjustment for the proposed measure suppression policy that could take into account any disparate effects of circumstances affecting hospitals around the country that would prompt us to suppress a measure. For example, COVID–19 affected different regions of the country at different rates depending on factors like time of year, geographic density, state and local policies, and health care system capacity. In future years and for future PHEs, should they arise, we also requested commenters' feedback on whether we should, rather than suppress a measure completely, consider a suppression policy with

more granular effects based on our assessment of the geographic effects of the circumstances, and if so, how region-based measure suppression could be accounted for within the program's scoring methodology.

The following is a summary of the public comments received on the proposed Flexibilities for the SNF VBP Program in Response to the Public Health Emergency Due to COVID–19 and our responses:

Comment: Several commenters expressed support for our proposal to establish a measure suppression policy for the PHE due to COVID–19 and for future PHEs. Many of the commenters noted that the proposed measure suppression factors are appropriate and comprehensive. One commenter suggested we include a review of state and regional performance in addition to national performance when evaluating the measure suppression factors in order to account for regional and state differences in the response to the PHE due to COVID–19. A few commenters recommended that the measure suppression should occur anytime a PHE is declared and extend through the end of that PHE, and one commenter specifically urged us to continue measure suppression for the PHE due to COVID–19 in FY 2023 to account for late surges that occurred in late CY 2020 and early CY 2021. A few commenters also expressed appreciation for our intent to standardize our suppression policy across settings and payment programs.

Response: We agree that the Measure Suppression Factors are appropriate. In our development of this measure suppression proposal, we considered that COVID–19 prevalence has not been identical across the country and that SNFs located in different regions have been affected differently during the PHE. Our proposal in the FY 2022 SNF PPS proposed rule was to adopt a measure suppression policy only for the duration of the COVID–19 PHE and to suppress the SNF readmission measure for only the FY 2022 SNF VBP Program, but we are continuing to consider options for mitigating any potential negative impacts the PHE due to COVID–19 may have on the FY 2023 Program.

Comment: A few commenters noted that CMS should be required to go through the rulemaking process when suppressing measures to ensure that the approach is fully vetted.

Response: We thank commenters and agree that we should use the rulemaking process if we consider suppressing one or more measures.

After considering the public comments, we are finalizing our measure suppression policy as proposed.

2. Suppression of the SNFRM for the FY 2022 SNF VBP Program Year

In the proposed rule, we proposed to suppress the SNFRM for the FY 2022 SNF VBP Program Year under proposed Measure Suppression Factor: (4) Significant national shortages or rapid or unprecedented changes in: (iii) Patient case volumes or facility-level case mix.

In response to the PHE for COVID–19, we granted an ECE for SNFs participating in the SNF VBP Program. Under the ECE, SNF qualifying claims for the period January 1, 2020 through June 30, 2020 are excepted from the calculation of the SNFRM. Because this ECE excepted data for 6 months of the performance period that we had previously finalized for the FY 2022 SNF VBP program year (84 FR 38822), we updated the performance period for that program year in the ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments, and Patient Protection and Affordable Care Act: Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment (''the September 2nd IFC'') (85 FR 54820). Specifically, we finalized that the new performance period for the FY 2022 SNF VBP program year would be April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020 because we believed that this period, which combined 9 months of data prior to the start of the PHE for COVID–19 and 3 months of data after the end of the ECE, would provide sufficiently reliable data for evaluating SNFs for the FY 2022 SNF VBP Program. However, analyses conducted by our contractor since the publication of the September 2nd IFC have found that when July–September 2020 SNF data are compared with July–September 2019 SNF data, the July–September 2020 SNF data showed 25 percent fewer SNF admissions and 26 percent fewer readmissions from a SNF to a hospital. These impacts have affected the reliability of the SNFRM. Generally speaking, the SNFRM's reliability decreases as the sample size and measured outcome (that is, readmissions) decrease. A drop of 25 percent in SNF admissions and 26 percent in readmissions to the hospital from July–September 2020 has significantly reduced the sample size needed to calculate both the measure cohort and outcome for the FY 2022 SNF VBP Program, thus jeopardizing the measure's reliability. Our contractor's analysis using FY 2019 data showed that such changes may lead to a 15 percent decrease in the measure reliability, assessed by the intra-class correlation coefficient (ICC). In addition, the current risk-adjustment model does not factor in COVID–19 or the fact that SNFs are treating different types of patients as a result of the COVID–19 PHE. Nearly 10 percent of SNF residents in July–September 2020 had a current or prior diagnosis of COVID–19, with uneven regional impacts. The SNFRM does not adjust for COVID–19 in the risk-adjustment methodology, as the measure was developed before the pandemic. As a result, risk-adjusted rates, which compare SNFs to each other nationally, are likely to reflect variation in COVID–19 prevalence rather than variation in quality of care. We do not believe that assessing SNFs on a quality measure affected significantly by the varied regional response to the COVID–19 PHE presents a clear picture of the quality of care provided by an individual SNF. The data also demonstrated other important changes in SNF patient case-mix during the PHE for COVID–19, including an 18 percent increase in the proportion of dually eligible residents and a 9 percent increase in the proportion of African-American SNF residents at the facility level. Dually eligible and African-American SNF residents have been disproportionately impacted by COVID, both in terms of morbidity and mortality. In the proposed rule, we stated we are conducting analyses to determine whether and how the SNFRM specifications may need to be updated to account for SNF residents with a primary or secondary diagnosis of COVID–19 for future program years. We also stated we plan to conduct analysis for the SNFPPR measure.

We considered whether we could propose to remove the July 1, 2020–September 30, 2020 data from the updated performance period for the FY 2022 SNF VBP Program Year and calculate the SNFRM using a 9-month performance period (April 1, 2019–December 31, 2019). To determine whether the measure would be reliable using data during this period, which would be closer to 8 months once we remove all SNF stays whose 30-day readmission risk-window extended to or after January 1, 2020, we performed reliability analyses using a formula that relates the reliability of a measure to its intraclass correlation coefficient (ICC), and found that an estimate of reliability using all 12 combinations of potential 8-month data periods from FY 2019 (that

is, October through May, November through June, and so on)[116] produces an average reliability estimate of 0.367, which is lower than our generally accepted minimum reliability threshold of 0.40.

We also considered substituting the July 1, 2020–September 30, 2020 period with an alternate data period; however, we are limited operationally in terms of which data may be used. Using data from further in the future would cause a delay in the calculation and dissemination of results for the FY 2022 Program. Such a delay could require us to make adjustments to the otherwise applicable Federal per diem rate paid to SNFs in FY 2022 on a delayed basis, which would be an extremely burdensome process for the MACs and a potentially confusing process for SNFs. While using older data is feasible, and we recognize that we adopted a performance period in the September 2nd IFC that duplicated the use of data from a previous performance period, our preference is to use as much new data as possible to assess SNF performance each year and to avoid, where feasible, using the same data as a performance period in multiple program years. Further revising the FY 2022 Program performance period to include older data would create a substantial overlap with the FY 2021 Program's performance period. Such a significant overlap would result in SNFs receiving payments in FY 2022 based largely on the same performance used to assess SNFs for the FY 2021 SNF VBP program year. Using over 80 percent of the same data twice as a performance period could result in some SNFs being penalized (or receiving a bonus) twice for nearly the same performance.

Therefore, due to concerns about the validity of the measure when calculated as currently specified on data during the PHE given the significant changes in SNF patient case volume and facility-level case mix described above, and lacking any viable alternatives, we proposed to suppress the use of SNF readmission measure data for purposes of scoring and payment adjustments in the FY 2022 SNF VBP Program Year, under the proposed Measure Suppression Factor (4) Significant national or regional shortages or rapid or unprecedented changes in: (iii) Patient case volumes or facility-level case mix.

[116] We assessed multiple 8-month data periods and averaged the reliability results to obtain a complete understanding of reliability across FY 2019, the most recent full year of production data available for analysis, and avoid potential issues caused by seasonality.

As we stated in the proposed rule, under this suppression policy, for all SNFs participating in the FY 2022 SNF VBP Program, we would use the previously finalized performance period and baseline period to calculate each SNF's RSRR for the SNFRM. Then, we would suppress the use of SNF readmission measure data for purposes of scoring and payment adjustments. Specifically, we proposed to change the scoring methodology to assign all SNFs a performance score of zero in the FY 2022 SNF VBP Program Year. This would result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. We would then apply the Low-Volume Adjustment policy as previously finalized in the FY 2019 SNF PPS final rule (83 FR 39278 through 39280). That is, if a SNF has fewer than 25 eligible stays during the performance period for a program year we would assign that SNF a performance score resulting in a net-neutral payment incentive multiplier. SNFs will not be ranked for the FY 2022 SNF VBP Program.

As we stated in the proposed rule, under this policy, we would reduce each participating SNF's adjusted Federal per diem rate for FY 2022 by 2 percentage points and award each participating SNF 60 percent of that 2 percent withhold, resulting in a 1.2 percent payback for the FY 2022 SNF VBP Program Year. We believe this continued application of the 2 percent withhold is required under section 1888(h)(5)(C)(ii)(III) of the Act and that a payback percentage that is spread evenly across all qualifying SNFs is the most equitable way to reduce the impact of the withhold in light of our proposal to award a performance score of zero to all SNFs. Those SNFs subject to the Low-Volume Adjustment policy would receive 100 percent of their 2 percent withhold per the previously finalized policy, increasing the overall payback percentage to an estimated 62.9 percent.

Further, we proposed to provide quarterly confidential feedback reports to SNFs and publicly report the SNFRM rates for the FY 2022 SNF VBP Program Year. However, we stated that we would make clear in the public presentation of those data that the measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the PHE for COVID–19 on the data used to calculate the measure. We proposed to codify this policy at § 413.338(g).

We invited public comment on this proposal. The following is a summary of the public comments we received on the proposed Suppression of the SNFRM for the FY 2022 SNF VBP Program Year, and our responses:

Comment: Many commenters expressed support for the proposal to suppress the SNFRM data for the purposes of scoring and payment adjustments for the FY 2022 SNF VBP Program Year under Measure Suppression Factor (4) Significant national or regional shortages or rapid or unprecedented changes in: (iii) Patient case volumes or facility-level case mix. Commenters agreed with our conclusion that the inclusion of data during the PHE due to COVID–19 would significantly affect the SNF readmission measure and not present a clear picture of the quality of care provided by an individual SNF. Additionally, they noted that CMS provided a fair path forward given the FY 2020 average reliability estimate using FY 2019 data was lower than the minimum reliability threshold.

Response: We thank the commenters for their support.

Comment: One commenter stated that the proposed measure suppression policy violates the provisions of section 1888(h)(6) of the Act, which funds value-based incentive payments via a reduction to SNFs' adjusted Federal per diem rates. The commenter also stated that the proposed suppression policy does not differentiate between high-performing and low-performing SNFs, and therefore, does not make value-based incentive payments as required by statute.

Response: As discussed in the proposed rule, we proposed to suppress the SNFRM due to the impacts of the COVID–19 PHE. Specifically, we have concerns about the validity of the measure when calculated as currently specified using data during the PHE given the significant changes in SNF patient case volume and facility-level case mix. We continue to believe that for purposes of scoring and payment adjustments under the SNF VBP Program, the SNFRM as impacted by the COVID–19 PHE should not be attributed to the participating facility positively or negatively, because the performance scores associated with the SNFRM would not accurately reflect facility performance for national comparison and ranking purposes given the variation in COVID–19 across different geographies and time periods and seen in fluctuating case volumes and case mix. However, due to the SNFRM being the only quality measure authorized for use in the FY 2022 SNF VBP, suppression of the SNFRM would mean we would not be able to calculate SNF performance scores for any SNF or to differentially rank SNFs. Therefore, we

proposed to change the scoring methodology to assign all SNFs a performance score of zero and effectively rank all SNFs equally in the FY 2022 SNF VBP Program Year.

Comment: Several commenters expressed concerns about publicly reporting SNFRM measure results for the FY 2022 SNF VBP Program Year despite the measure being suppressed because they believe that the publicly reported information may cause public confusion and misrepresent quality of care for a particular SNF. Two commenters also noted that the SNFRM does not adjust for COVID–19 diagnoses and should not be publicly reported until it does.

Response: We proposed to suppress the SNFRM due to the impacts of the COVID–19 PHE for purposes of scoring and payment adjustments because of our concern that we would not be able to make fair, national comparisons of SNFs across the country or to fairly and accurately rank SNFs based only on quality performance and not other exogenous factors related to the PHE for COVID–19. We also believe it is important to balance fairness in performance-based payments with the public's interest in and need for transparency of data from during the COVID–19 PHE, including hospital readmissions information for SNF patients. Therefore, we intend to make the data available on the Provider Data Catalogue (*https://data.cms.gov/provider-data/*) website. We will make clear in the public presentation of the data that the measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the PHE due to COVID–19. We will also appropriately caveat the data in order to mitigate public confusion and avoid misrepresenting quality of care. SNFs that qualify for the low-volume adjustment policy will not have their risk-standardized readmission rate publicly displayed and an explanatory footnote will be available instead.

We also understand the commenters' concern that the SNFRM does not currently adjust for COVID–19 diagnoses in the risk-adjustment methodology, as the measure was developed before the PHE. We have conducted internal analyses that indicated a large number of patients who were admitted to SNFs had a primary or secondary diagnosis of COVID–19 during their prior proximal hospitalization. The SNFRM does not currently account for COVID–19, and we believe it is important to more fully assess the impact of COVID–19 on the SNFRM, including the following: Whether we should add COVID–19 as a risk-adjustment variable, exclude COVID–19 patients from the denominator, or exclude COVID–19 readmissions from the outcome.

After considering the public comments, we are finalizing our proposal to suppress the SNFRM for the FY 2022 SNF VBP Program Year as proposed and codifying it, as well as the scoring and payment policies we are finalizing for FY 2022, at § 413.338(g) of our regulations.

3. Revision to the SNFRM Risk Adjustment Lookback Period for the FY 2023 SNF VBP Program

In the FY 2021 SNF PPS final rule (85 FR 47624), we finalized the FY 2023 Program performance period as FY 2021 (October 1, 2020–September 30, 2021). In the FY 2016 SNF PPS final rule (80 FR 46418), we finalized that the risk-adjustment model would account for certain risk-factors within 365 days prior to the discharge from the hospital to the SNF (a 365-day lookback period). Under the COVID–19 ECE, SNF qualifying claims for the period January 1, 2020–June 30, 2020 are excepted from the calculation of the SNFRM; using FY 2021 data, this results in at least 3 months of lookback data being available for all SNF stays included in the measure without extending into or beyond June 30, 2020. We proposed instead a 90-day lookback period for risk-adjustment in the FY 2023 performance period (FY 2021 data) only. We stated in the proposed rule that using a 90-day risk-adjustment period would allow us to use the most recent claims available for risk-adjustment, and an identical risk-adjustment lookback period for all stays included in the measure. It also allows us to avoid combining data from both prior to and during the COVID–19 PHE in the risk-adjustment lookback period, which would be necessary if we attempted to maintain a 12-month lookback period due to the COVID–19 ECE. Using a 90-day lookback period for risk-adjustment would allow us to look back 90 days prior to the discharge from the hospital to the SNF for each SNF stay. Analyses conducted on FY 2019 performance data found that when compared to the 365-day lookback period traditionally used, a 90-day lookback period resulted in similar model performance (that is, the C-statistic was nearly identical). We also considered similarly reducing the risk-adjustment lookback period for the applicable FY 2023 Program baseline year which would align the risk-adjustment lookback period for the baseline and performance years in the FY 2023 Program; we invited comments on this consideration.

We invited public comment on the proposed updates to the risk-adjustment lookback period for the FY 2023 performance period.

The following is a summary of the public comments received on the proposed 90-day SNFRM risk-adjustment lookback period for the FY 2023 SNF VBP Program performance period and our responses:

Comment: One commenter recommended continued testing of the 90-day risk-adjustment lookback period for FY 2023, stating that this approach worked well using FY 2019 performance data. The commenter stated that testing with FY 2020 data and analyses of regional effects based on COVID–19 impacts would be informative before finalizing this approach.

Response: We acknowledge the commenter's suggestion to continue testing the 90-day risk-adjustment lookback period for FY 2023 and agree with the importance of continued testing. We note that the analyses we conducted on FY 2019 performance data resulted in nearly identical C-statistics, indicating that the model using a 90-day lookback period performed similarly to the model using a traditional 365-day lookback period. We will continue to test FY 2020 data in a similar fashion, but we believe the results from the FY 2019 data illustrate the model performance for a 90-day lookback period for the FY 2023 performance period.

After considering the public comments, we are finalizing our proposal to use a 90-day lookback period for risk-adjustment in the FY 2023 performance period (FY 2021).

4. Summary of Comments Received on Potential Future Measures for the SNF VBP Program

On December 27, 2020, Congress enacted the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260). Section 111(a)(1) of Division CC of the CAA amends section 1888(h)(1) of the Act to, with respect to payments for services furnished on or after October 1, 2022, preclude the SNF VBP from applying to a SNF for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the facility for the performance period for the applicable fiscal year, or measures that apply to the facility for the performance period for the applicable fiscal year. Section 111(a)(2) of the CAA amended section 1888(h)(2)(A) of the Act to, with respect to payments for services furnished on or after October 1, 2023, require the Secretary to apply the readmission measure specified under

section 1888(g)(1) of the Act, and allow the Secretary to apply up to 9 additional measures determined appropriate, which may include measures of functional status, patient safety, care coordination, or patient experience. To the extent that the Secretary decides to apply additional measures, section 1888(h)(2)(A)(ii) of the Act, as amended by section 111(a)(2)(C) of the CAA, requires the Secretary to consider and apply, as appropriate, quality measures specified under section 1899B(c)(1) of the Act. Finally, section 111(a)(3) of the CAA amended section 1888(h) of the Act by adding a new paragraph (12), which requires that the Secretary apply a process to validate the measures and data submitted under the SNF VBP and the SNF QRP, as appropriate, which may be similar to the process specified under the Hospital Inpatient Quality Reporting (IQR) Program for validating inpatient hospital measures. In the proposed rule, we solicited input from stakeholders regarding which measures we should consider adding to the SNF VBP Program. We intend to use future rulemaking to address these new statutory requirements.

Currently, the SNF VBP Program includes only a single quality measure, the SNFRM, which we intend to transition to the SNFPPR measure as soon as practicable. Both the SNFRM and SNFPPR assess the risk-adjusted rate of readmissions to hospitals, for SNF residents within 30 days of discharge from a prior hospital stay. Consistent with amended section 1888(h)(2)(A)(ii) of the Act, in considering which measures might be appropriate to add to the SNF VBP Program, we are considering additional clinical topics such as measures of functional status, patient safety, care coordination, and patient experience, as well as measures on those topics that are utilized in the SNF Quality Reporting Program (QRP). For more information about the SNF QRP measures, please visit *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

We are also considering measures on clinical topics that are not included in the SNF QRP's measure set because we believe that other clinical topics would be helpful to our efforts to robustly assess the quality of care furnished by SNFs.

In expanding the SNF VBP measure set, we are also considering measures that we already require for Long-Term Care Facilities (LTCFs), which include both SNFs and nursing facilities (NFs), to collect and report under other initiatives. Approximately 94 percent of LTCFs are dually certified as both a SNF and NF (Provider Data Catalog Nursing Homes and Rehab Services Provider Information File January 2021) (*https://data.cms.gov/provider-data/dataset/4pq5-n9py*). The vast majority of LTCF residents are also Medicare beneficiaries, regardless of whether they are in a Medicare Part A SNF stay, because they are enrolled in Medicare Part B and receive Medicare coverage of certain services provided by the LTCF even if they are a long-term care resident. Therefore, we believe that expanding the SNF VBP measure set to assess the quality of care that SNFs provide to all residents of the facility, regardless of payer, would best represent the quality of care provided to all Medicare beneficiaries in the facility. We requested public comment on whether the measures in an expanded SNF VBP measure set should require SNFs to collect data on all residents in the facility, regardless of payer.

We identified the measures listed in Table 30 as measures we could add to the SNF VBP Program measure set, and we sought comment on those measures, including which of those measures would be best suited for the program. We also solicited public comment on any measures or measure concepts that are not listed in Table 30 that stakeholders believe we should consider for the SNF VBP Program. In considering an initial set of measures with which SNFs should largely be familiar (through the SNF QRP, 5-Star Rating Program and/or the Nursing Home Quality Initiative (NHQI)), we believe we can implement a measure set that would impose minimal additional burden on SNFs.

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TABLE 30: Quality Measures Under Consideration for an Expanded Skilled Nursing Facility Value-Based Purchasing Program

Meaningful Measure Area	NQF	Quality Measure
Minimum Data Set		
Functional Outcomes	A2635	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients*
Functional Outcomes	A2636	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients*
Preventable Healthcare Harm	0674	Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)**
Preventable Healthcare Harm	0679	Percent of High Risk Residents with Pressure Ulcers (Long Stay)**
Functional Outcomes	N/A	Percent of Residents Whose Ability to Move Independently Worsened (Long Stay)**
Functional Outcomes	N/A	Percent of Residents Whose Need for Help with Activities of Daily Living Has Increased (Long Stay)**
Transfer of Health Information and Interoperability	N/A	Transfer of Health Information to the Provider–Post Acute Care *
Medication Management	N/A	Percentage of Long-Stay Residents who got an Antipsychotic Medication**
Medicare Fee-For-Service Claims Based Measures		
Community Engagement	3481	Discharge to Community Measure-Post Acute Care Skilled Nursing Facility Quality Reporting Program*
Patient-focused Episode of Care	N/A	Medicare Spending per Beneficiary (MSPB)-Post Acute Care Skilled Nursing Facility Quality Reporting Program*
Healthcare-Associated Infections	N/A	Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization Measure~
Admissions and Readmissions to Hospitals	N/A	Number of hospitalizations per 1,000 long-stay resident days (Long Stay)**
Patient-Reported Outcome-Based Performance Measure		
Functional Outcomes	N/A	Patient-Reported Outcomes Measurement Information System [PROMIS]-PROMIS Global Health, Physical
Survey Questionnaire (similar to Consumer Assessment of Healthcare Providers and Systems (CAHPS))		
Patient's Experience of Care	2614	CoreQ: Short Stay Discharge Measure
Payroll Based Journal		
N/A	N/A	Nurse staffing hours per resident day: Registered Nurse (RN) hours per resident per day; Total nurse staffing (including RN, licensed practical nurse (LPN), and nurse aide) hours per resident per day**

** Measures adopted in the SNF Quality Reporting Program (QRP).*
*** These measures are reported on the Nursing Home Care Compare website (https://www.medicare.gov/care-compare/).*
~ Measure discussed in section VII.C.1 of this final rule for adoption in the SNF QRP.

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In addition to the staffing measures listed in Table 30 that focus on nurse staffing hours per resident day and that are currently reported on the Nursing Home Care Compare website, we indicated in the proposed rule that we are also interested in measures that focus on staff turnover. We have been developing measures of staff turnover for data that are required to be submitted under section 1128I(g)(4) of the Act, with the goal of making the information publicly available. Through our implementation of the Payroll-Based Journal (PBJ) staffing data collection program, we have indicated that we will be reporting rates of employee turnover in the future (for more information on

this program, see CMS memorandum QSO–18–17–NH [117]). As we plan to report employee turnover information in the near future, we also sought comment on inclusion of these measures in the SNF VBP Program.

We are also considering two patient-reported measures (the PROMIS measure and the CoreQ patient experience of care measure), as listed in Table 30, to assess residents' views of their healthcare.

The CoreQ: Short Stay Discharge Measure calculates the percentage of individuals discharged in a 6-month time period from a SNF, within 100 days of admission, who are satisfied with their SNF stay. This patient reported outcome measure is based on the CoreQ: Short Stay Discharge questionnaire that utilizes four items: (1) In recommending this facility to your friends and family, how would you rate it overall; (2) Overall, how would you rate the staff; (3) How would you rate the care you receive; (4) How would you rate how well your discharge needs were met. For additional information about the CoreQ: Short Stay Discharge Measure, please visit *https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=3436.*

We welcomed public comment on future measures for the SNF VBP Program, and on whether the measures in an expanded SNF VBP measure set should require SNFs to collect data on all residents in the facility, regardless of payer.

The following is a summary of the public comments received on the Request for Comments on Potential Future Measures for the SNF VBP Program:

Comment: Many commenters generally supported the adoption of new measures in the SNF VBP Program. However, many commenters did not support the Percentage of Long-Stay Residents who got an Antipsychotic Medication measure noting concerns with disincentivizing clinically appropriate access to FDA-approved medications, impact on patient care and outcomes, and that the measure is not NQF-endorsed.

A few commenters supported CoreQ: Short Stay Discharge Measure (CoreQ) stating it measures outcomes important to residents. A few commenters expressed concerns that CoreQ may not fully reflect the patient experience and that the measure's questions are vague. A few commenters recommended the use of CAHPS Nursing Home Resident and Family member surveys instead of the CoreQ questionnaire because commenters believe it provides more complete and comprehensive information about a resident's experience and is developed through a more rigorous and independent process. A few commenters supported inclusion of the Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization Measure (HAI) in the SNF VBP Program to support and prioritize improved patient outcomes. A few commenters supported the inclusion of the Medicare Spending per Beneficiary (MSPB) measure because the measure captures elements of care coordination that are important to beneficiaries and the Medicare program. A few commenters did not support the MSPB measure, citing their belief that costs can vary depending upon beneficiary needs and that the measure does not reflect the immediate need or interests of residents or families.

With respect to measures related to staffing turnover, several commenters supported staffing measures that assess the appropriate level of licensed clinical staff such as those that can be derived from the Payroll-Based Journal (PBJ) data collection program, including Registered Nurse (RN) hours per resident per day and total nurse staffing (including RN, licensed practical nurse (LPN), and nurse aide) hours per resident per day. While they supported these PBJ-based staffing measures, commenters strongly recommended that CMS consider staffing turnover to assess patterns and consistency in staffing levels as they are associated with and indicative of quality and safety issues, and high turnover could lead to low quality of care and could disrupt the health, safety, and well-being of patients.

Several commenters expressed some concerns with the inclusion of a staffing measure. One commenter recommended that staffing measures should focus on consistent staffing rather than just collecting data on the number of nursing staff by type. One commenter noted that staffing measures are important to report but expressed concern that staffing measures have not been evaluated for use in value-based purchasing programs, and another commenter suggested that staffing requirements vary across states. A few commenters expressed concerns with the burden of reporting a staffing measure. A few commenters recommended delaying the addition of a staffing measure due to the COVID–19 pandemic.

One commenter supported the inclusion of Patient Reported Outcome Measures (PROMs) as soon as possible and appreciated the consideration of the two PROMs (PROMIS and the CoreQ patient experience of care) for future years. One commenter supported the use of the PROMIS questionnaire, but noted additional resources would be needed for implementation. One commenter recommended that the patient experience measure use minimal questions and take into account the role of caregivers in helping complete the surveys. One commenter recommended that any PROMIS measure considered be reviewed by NQF; this commenter also noted that PROMIS measures were not developed for institutional populations and that CMS should consider the burden to collect, store, and transmit these data.

Many commenters supported the use of patient experience measures in the SNF VBP Program. One commenter recommended that patient experience measures be adjusted for respondent characteristics. One commenter recommended excluding beneficiaries in managed care plans from a patient experience measure, expressing concern that beneficiaries may be unsatisfied with how their stay was managed by their Managed Care/Medicare Advantage Plan and that this would reflect negatively towards the SNF on a patient-reported outcome survey. A few commenters recommended delaying the implementation of patient experience surveys due to the COVID–19 pandemic. One commenter did not support the two patient-reported measures, noting the survey process already includes residents, and suggested that we focus on expanding the survey protocol instead of adding a new measure. This commenter also stated that the questions on the CoreQ measure may not sufficiently capture customer dissatisfaction. Instead, this commenter recommended strengthening and expanding the current CMS survey protocol. One commenter recommended the development and adoption of a standardized patient experience survey for the SNF QRP before potentially being adopted for the SNF VBP Program.

A few commenters recommended inclusion of the NQF 3481, Discharge to Community Measure-Post Acute Care Skilled Nursing Facility Quality Reporting Program measure. A few commenters recommended inclusion of the NQF A2636, Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients measure. One commenter recommended inclusion of the Preventable Healthcare Harm—0674 Percent of Residents Experiencing One or More Falls with Major Injury

[117] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-17-NH.pdf.*

measure. One commenter recommended inclusion of the Transfer of Health Information (HI) and Interoperability—Transfer of Health Information to the Provider-Post Acute Care measure to advance CMS' goals of improving patient safety through adoption of EHR and FHIR standards.

Several commenters recommended aligning SNF VBP readmissions measures with the readmission measures used by other CMS programs, including the SNF QRP. One commenter recommended criteria for evaluating which measures should be adopted in the SNF VBP Program, including measures with NQF endorsement, high impact on outcomes/performance, resident quality of life focus, low administrative burden, statistically significant variation among providers, risk-adjustment for social risk factors, and appropriate application to the SNF population and their health status. Many commenters recommended that any new measures added to SNF VBP be NQF-endorsed. One commenter recommended that any new measures should include descriptions of the measure's weight and scoring requirements. Another commenter recommended that CMS balance the need for new quality measures with reducing administrative burden and duplicative reporting in other quality programs. A few commenters recommended a phased approach to adding new measures to the SNF VBP Program. One commenter recommended limiting the number of measures added in the first year in order to avoid diluting the Program's clear focus on readmissions. One commenter noted that adding nine additional measures to the SNF VBP Program would be too aggressive in expanding the measures and recommended adding two or three measures suggesting this would be easier to integrate and allow providers time to prepare. One commenter recommended delaying the addition of measures until after the PHE has ended.

Several commenters expressed support for collecting performance data across payers. One commenter supported that any and all new measures require data on all SNF residents regardless of payer. One commenter did not support moving to all-payer for most measures but did support the inclusion of all residents across payers in the patient experience measure to increase the sample size for an important measure of quality care. A few commenters did not support the inclusion of nursing home residents in the calculation of measure results for the SNF VBP Program noting differences in policies such as limitations on days of care under Medicare Advantage. A few commenters recommended that not all measures should apply to all residents within a nursing home and that there should be a distinction between measures for short-term and long-term stay residents to accommodate the different goals between these two types of residents.

One commenter recommended that CMS focus on adding outcomes-based measures to the SNF VBP Program. A few commenters did not support any new measures based on self-reported MDS data, believing these data are inaccurate. One commenter recommended that measures should incorporate social determinants of health when feasible and applicable. One commenter did not support the inclusion of utilization-based measures.

A few commenters recommended future consideration of new measures for frailty, patient reported outcomes, health equity, and pain, including the following measures: Satisfaction with Participation in Social Roles; Ability to Participate in Social Roles and Activities; Cognitive Function—Abilities; General Life Satisfaction; General Self-Efficacy: Self-Efficacy for Managing Chronic Conditions—Managing Daily Activities, Self-Efficacy for Managing Chronic Conditions—Managing Symptoms, and Self-Efficacy for Managing Chronic Conditions—Managing Medications and Treatment. Another commenter recommended measures of patient and workforce safety and reliability, clinical quality, and caregiver engagement that are evidence-based, targeted, and meaningful to patients and caregivers; this commenter also encouraged the collection of data based on key variables of inequities in patient care for all types of measures. One commenter recommended a small set of population-based measures tied to outcomes, patient-experience and resource use that are not burdensome to report. One commenter recommended that CMS add a risk-adjustment variable for socioeconomic status to the hospital readmission measure for the SNF VBP. One commenter recommended a measure focused on resident ''dumping.'' One commenter recommended a measure comparing the Minimum Data Set section GG: Functional Abilities and Goals with length of stay to develop an outcome ratio to account for patient complexity for facilities with short-term transitional care patients.

One commenter recommended that CMS take steps to ensure the accuracy of reported data. One commenter recommended further clarification of how measure collection may impact providers with low-volume Medicare beneficiaries and whether this program will be extended to nursing facilities. One commenter recommended prioritizing value for residents by returning a higher percentage of withheld funds and utilizing measures that more directly measure outcomes that are important to SNF residents.

Response: We thank the commenters for their responses to this request for comments on potential future measures for the SNF VBP Program. We will take all of this feedback into consideration as we develop our policies for future rulemaking. In addition, as previously indicated, we plan to report SNF employee turnover information in the near future.

C. SNF VBP Performance Period and Baseline Period

1. Background

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for a discussion of our considerations for determining performance periods under the SNF VBP Program. In the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), we adopted a policy whereby we will automatically adopt the performance period and baseline period for a SNF VBP Program Year by advancing the performance period and baseline period by 1 year from the previous program year.

2. Updated Performance Period for the FY 2022 SNF VBP

In response to the PHE for COVID–19, we granted an ECE for SNFs participating in the SNF VBP Program. Under the ECE, SNF qualifying claims for the period January 1, 2020–June 30, 2020 are excepted from the calculation of the SNFRM. Because this ECE excepted data for 6 months of the performance period that we had previously finalized for the FY 2022 SNF VBP Program Year (84 FR 38822), we updated the performance period for that program year in the ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments, and Patient Protection and Affordable Care Act: Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment (''the September 2nd IFC'') (85 FR 54820). Specifically, we finalized that the new performance period for the FY 2022 SNF VBP Program Year would be April 1, 2019–December 31, 2019 and July 1, 2020–September 30, 2020 because we believed that this period, which combined 9 months of data prior to the

start of the PHE for COVID–19 and 3 months of data after the end of the ECE, would provide sufficiently reliable data for evaluating SNFs for the FY 2022 SNF VBP Program. The following is a summary of the public comments received from the September 2nd IFC regarding the updated FY 2022 performance period.

Comment: One commenter expressed support for the updated performance period, agreeing that using only 6 months of data would not provide reliable results. This commenter encouraged CMS to extend the ECE to include all of 2020 and suspend the SNFRM measure for FY 2022.

Response: We thank this commenter for their support. Additionally, we refer readers to section VIII.B.1. and VIII.B.2. of this final rule, where we have finalized several flexibilities that result in suppressing the SNFRM for FY 2022. Regarding the commenter's suggestion to extend the ECE in section VIII.B.1. of the FY 2022 SNF PPS proposed rule (86 FR 20007), we noted that while we considered extending the ECE, this option would result in less than 12 months of data being used to calculate the single readmissions measure in the Program for multiple program years, which we do not believe would provide an accurate assessment of the quality of care provided in SNFs. This option would also leave no comprehensive data available for us to provide confidential performance feedback to providers nor for monitoring and to inform decision-making for potential future programmatic changes.

Comment: One commenter opposed this updated performance period, noting that CMS would not receive reliable data from CY 2020, and recommended that CMS not score facilities for FY 2020 performance or make associated payment adjustments for the FY 2022 SNF VBP Program and resume the program in subsequent years once reliable performance data consistent with measure specifications are available. Another commenter also expressed concern that any CY 2020 data would be unreliable and urged CMS to extend the ECE and suspend the SNFRM for FY 2022.

Response: At the time of the publication of the September 2nd IFC, we adopted a performance period that we believed would provide sufficiently reliable data for evaluating SNF performance (85 FR 54837) and would be the most operationally feasible option that included 12 months of data. Since the publication of the September 2nd IFC, additional data have become available, and we have conducted analyses on the impact of the COVID–19 PHE. As described more fully in section VIII.B.2. of this final rule, we continue to have concerns about the validity of the measure when calculated as currently specified on data during the PHE (specifically, July 1, 2020 through September 30, 2020) as well as the reliability of the measure when calculated using data from a shorter timeframe. Further, we considered many alternatives to the performance period we adopted in the September 2nd IFC and believed that none were sufficient for scoring and payment. Therefore, we are finalizing our proposal to suppress the SNFRM for the FY 2022 SNF VBP Program Year for scoring and payment purposes. However, for the purposes of measure rate calculation and public reporting, to ensure we are providing providers and the public with as much information as possible, we believe the performance period adopted in the September 2nd IFC is the most appropriate given the alternatives.

Upon consideration of public comments, we are finalizing the revised Performance Period for the FY 2022 SNF VBP Program (April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020) as established in the September 2nd IFC. This performance period will be used to calculate each SNF's RSRR for the SNFRM and we will publicly report these results on the Provider Data Catalogue website (*https://data.cms.gov/provider-data/*), while making it clear in the public presentation of those data that we are suppressing the use of those data for purposes of scoring and payment adjustments in the FY 2022 SNF VBP Program.

3. Performance Period for the FY 2023 SNF VBP Program

In the FY 2021 SNF PPS final rule (85 FR 47624), we finalized that the performance period for the FY 2023 SNF VBP Program Year would be October 1, 2020–September 30, 2021 (FY 2021) and the baseline period would be FY 2019 (October 1, 2018–September 30, 2019). We did not propose any updates to the performance period and baseline period previously finalized for FY 2023.

Comment: One commenter did not support the previously finalized performance period for FY 2023 noting that it includes CY 2020 data that is not adjusted to account for the impact of COVID–19 and is unreliable.

Response: We are considering whether we should make changes to the SNFRM specifications to account for changes in SNF admission and/or hospital readmission patterns that we have observed during the COVID–19 PHE. Any substantive changes to the measure specifications would be proposed in future rulemaking.

We noted in the proposed rule (86 FR 20011 through 20012) that we had considered alternatives to the previously finalized performance period for FY 2023. We specifically considered modifying the performance period for the FY 2023 program year to Calendar Year 2021 (January 1, 2021 through December 31, 2021). However, CY 2021 data are available later than FY 2021 data and would likely result in a delay calculating SNFRM scores for SNFs and a subsequent delay in the application of payment incentives for the FY 2023 program year.

We acknowledge that the COVID–19 PHE extends into both performance period options. As noted in section VIII.B.2., we intend to conduct analyses to determine whether and how the SNFRM specifications may need to be updated to account for SNF residents with a diagnosis of COVID–19 for future program years. Following the completion of these analyses, SNF readmission measure specifications may account for changes in SNF admission and/or hospital readmission patterns that we have observed during the PHE, if needed.

We invited public comment on this alternative to the previously finalized performance period for the FY 2023 SNF VBP program but did not receive any comments on this alternative.

4. Performance Period and Baseline Period for the FY 2024 SNF VBP Program

Under the policy finalized in the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), for the FY 2024 program year, the performance period would be FY 2022 and the baseline period would be FY 2020. However, under the ECE, SNF qualifying claims for a 6-month period in FY 2020 (January 1, 2020 through June 30, 2020) are excepted from the calculation of the SNFRM, which means that we will not have a full year of data to calculate the SNFRM for the FY 2020 baseline period. Moreover, as described in more detail in section VIII.B.2. of this final rule, we are finalizing the suppression of the SNFRM for the FY 2022 program year, in part because there are concerns about the validity of the measure when calculated as currently specified on data during the PHE (specifically, July 1, 2020 through September 30, 2020) given the significant changes in SNF patient case volume and facility-level case mix described above. As the SNF VBP

Program uses only a single measure calculated on 1 year of data and uses each year of data first as a performance period and then later on as a baseline period in the Program, the removal of 9 months of data in light of the COVID–19 PHE as described above will necessarily result in data being used more than once in the Program. Therefore, to ensure enough data are available to reliably calculate the SNFRM, we proposed that FY 2019 data be used for the baseline period for the FY 2024 program year. We also considered using FY 2021, which will be the baseline period for the FY 2025 program year under our current policy. However, it is operationally infeasible for us to calculate the baseline for the FY 2024 program year using FY 2021 data in time to establish the performance standards for that program year at least 60 days prior to the start of the performance period, as required under section 1888(h)(3)(C) of the Act.

We invited public comment on this proposal. The following is a summary of the public comments received on the proposed baseline period for the FY 2024 SNF VBP program and our responses:

Comment: One commenter noted concern that using FY 2019 data as the baseline period for the FY 2024 program year may not provide relevant or comparable data for the performance period in FY 2024. Therefore, the commenter did not support the proposed FY 2024 baseline period.

Response: Due to measure reliability and operational feasibility considerations noted in section VIII.C.5. of this final rule, as well as FY 2019 data were not impacted by the COVID–19 PHE, we continue to believe that using FY 2019 data as the baseline period for the FY 2024 performance period is appropriate. We are also conducting testing to assess whether any updates should be made to the specifications of the SNF readmission measure to account for changes in SNF admission and/or hospital readmission patterns that we have observed during the PHE which may impact the FY 2024 performance period's comparability to the FY 2024 baseline period. Additionally, we believe that using FY 2019 data will be both relevant and comparable as the FY 2019 SNFRM data would reflect care delivered prior to the start of the Secretary's declaration of a PHE for COVID–19. With regard to the FY 2024 performance period, we believe facilities will have had time to adapt to the changes in care delivery needed to respond to the COVID–19 pandemic.

After considering the public comments, we are finalizing our proposal to use FY 2019 data for the FY 2024 baseline period as proposed.

D. Performance Standards

1. Background

We refer readers to the FY 2017 SNF PPS final rule (81 FR 51995 through 51998) for a summary of the statutory provisions governing performance standards under the SNF VBP Program and our finalized performance standards policy. We adopted the final numerical values for the FY 2022 performance standards in the FY 2020 SNF PPS final rule (84 FR 38822) and adopted the final numerical values for the FY 2023 performance standards in the FY 2021 SNF PPS final rule (85 FR 47625). We also adopted a policy allowing us to correct the numerical values of the performance standards in the FY 2019 SNF PPS final rule (83 FR 39276 through 39277).

We did not propose any changes to these performance standard policies in the proposed rule.

2. SNF VBP Performance Standards Correction Policy

In the FY 2019 SNF PPS final rule (83 FR 39276 through 39277), we finalized a policy to correct numerical values of performance standards for a program year in cases of errors. We also finalized that we will only update the numerical values for a program year one time, even if we identify a second error, because we believe that a one-time correction will allow us to incorporate new information into the calculations without subjecting SNFs to multiple updates. We stated that any update we make to the numerical values based on a calculation error will be announced via the CMS website, listservs, and other available channels to ensure that SNFs are made fully aware of the update. In the FY 2021 SNF PPS final rule (85 FR 47625), we amended the definition of ''Performance standards'' at § 413.338(a)(9), consistent with these policies finalized in the FY 2019 SNF PPS final rule, to reflect our ability to update the numerical values of performance standards if we determine there is an error that affects the achievement threshold or benchmark. We did not propose any changes to the performance standards correction policy in the proposed rule.

3. Performance Standards for the FY 2024 Program Year

As discussed in section VIII.C.5. of this final rule, we are finalizing our proposal to use FY 2019 data for the baseline period for the FY 2024 program year. Based on this updated baseline period and our previously finalized methodology for calculating performance standards (81 FR 51996 through 51998), the final numerical values for the FY 2024 program year performance standards are as follows:

TABLE 31: Final FY 2024 SNF VBP Program Performance Standards

Measure ID	Measure Description	Achievement Threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79271	0.83033

E. SNF VBP Performance Scoring

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52000 through 52005) for a detailed discussion of the scoring methodology that we have finalized for the Program. We also refer readers to the FY 2018 SNF PPS final rule (82 FR 36614 through 36616) for discussion of the rounding policy we adopted. We also refer readers to the FY 2019 SNF PPS final rule (83 FR 39278 through 39281), where we adopted: (1) A scoring policy for SNFs without sufficient baseline period data, (2) a scoring adjustment for low-volume SNFs, and (3) an extraordinary circumstances exception policy.

In the FY 2022 SNF PPS proposed rule, we proposed to suppress the SNFRM for the FY 2022 program year due to the impacts of the PHE for COVID–19. Specifically, for FY 2022 scoring, we proposed that for all SNFs participating in the FY 2022 SNF VBP Program, we would use performance period data from April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020 and baseline period data from October 1, 2017 through September 30, 2018,

which we previously finalized to calculate each SNF's RSRR for the SNFRM. Then, we would assign all SNFs a performance score of zero. This would result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. We stated in the proposed rule that we would then apply the Low-Volume Adjustment policy as previously finalized in the FY 2019 SNF PPS final rule (83 FR 39278 through 39280). That is, if a SNF has fewer than 25 eligible stays during the performance period for a program year we would assign that SNF a performance score resulting in a net-neutral payment incentive multiplier. SNFs would not be ranked for the FY 2022 SNF VBP Program.

The following is a summary of the public comments received on the proposal to use a special scoring policy for FY 2022 and our responses:

Comment: One commenter expressed support for our proposed adjustments to FY 2022 scoring and payments if the SNFRM is suppressed given the unprecedented circumstances caused by the PHE due to COVID–19.

Response: We thank this commenter for its support.

Comment: One commenter suggested an alternative of basing payment adjustments on performance scores from the FY 2021 SNF VBP Program Year.

Response: We did consider using alternative performance periods for the FY 2022 SNF VBP Program Year, as noted in section VIII.B.2. of the proposed rule. However, we believe using entirely the same data (both the exact same performance and baseline period data) for both the FY 2021 and FY 2022 program years would provide no new information for SNFs or the public, particularly information during the COVID–19 PHE, and may have the unintended effect of mitigating incentives for providers to improve between the overlapping program years or unfairly rewarding or penalizing SNFs by repeating the FY 2021 program.

Comment: Several commenters expressed concern that our proposed measure suppression and scoring policy for FY 2022 might violate sections 1888(h)(4)(B) and 1888(h)(5)(C)(ii)(II)(cc) of the Act, which state that the Secretary shall rank SNF performance scores from low to high, and for SNFs in the lowest 40 percent ranking, to apply a payment rate for services less than the payment rate that would otherwise apply without the SNF VBP Program.

Response: As discussed in section VIII.D.2. of the proposed rule and this final rule, we proposed and are finalizing suppression of the SNFRM due to the impacts of the COVID–19 PHE. Specifically, we have concerns about the validity of the measure when calculated as currently specified on data during the PHE given the significant changes in SNF patient case volume and facility-level case mix and lacking any viable alternatives. We stated in the proposed rule our belief that for purposes of scoring and payment adjustments under the SNF VBP Program, the SNFRM as impacted by the COVID–19 PHE should not be attributed to the participating facility positively or negatively. We believe that using SNFRM data that has been impacted by the PHE due to COVID–19 could result in performance scores that do not accurately reflect SNF performance for making national comparisons and ranking purposes given the variation in COVID–19 across different geographies and time periods and seen in fluctuating case volumes and case mix. Due to the SNFRM being the only quality measure authorized for use in the FY 2022 SNF VBP, suppression of the SNFRM would mean we would not be able to calculate SNF performance scores for any SNF nor to differentially rank SNFs. Therefore, we proposed to change the scoring methodology to assign all SNFs a performance score of zero and effectively rank all SNFs equally in the FY 2022 SNF VBP Program Year.

After considering the public comments, we are finalizing our proposed special scoring policy for the FY 2022 program year as proposed and codifying it at § 413.338(g) of our regulations.

F. SNF Value-Based Incentive Payments

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36616 through 36621) for discussion of the exchange function methodology that we have adopted for the Program, as well as the specific form of the exchange function (logistic, or S-shaped curve) that we finalized, and the payback percentage of 60 percent. We adopted these policies for FY 2019 and subsequent fiscal years.

We also discussed the process that we undertake for reducing SNFs' adjusted Federal per diem rates under the Medicare SNF PPS and awarding value-based incentive payments in the FY 2019 SNF PPS final rule (83 FR 39281 through 39282).

As discussed in sections VIII.B.2. and VIII.E of this final rule, we are finalizing the suppression of the SNFRM for the FY 2022 program year and assigning all SNFs a performance score of zero, which would result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier.

In the proposed rule, we proposed to reduce each participating SNF's adjusted Federal per diem rate for FY 2022 by 2 percentage points and to award each participating SNF 60 percent of that 2 percent withhold, resulting in a 1.2 percent payback for the FY 2022 program year. We believe this continued application of the 2 percent withhold is required under section 1888(h)(5)(C)(ii)(III) of the Act and that a payback percentage that is spread evenly across all SNFs is the most equitable way to reduce the impact of the withhold in light of our proposal to award a performance score of zero to all SNFs. We proposed that those SNFs subject to the Low-Volume Adjustment policy would receive 100 percent of their 2 percent withhold per the previously finalized policy, increasing the overall payback percentage to an estimated 62.9 percent. We proposed to codify this policy at § 413.338(g).

We invited public comment on this proposed change to the SNF VBP payment policy for the FY 2022 program year.

The following is a summary of the public comments received on the proposed SNF Value-Based Incentive Payments and our responses:

Comment: The majority of commenters supported suppressing the SNFRM due to the COVID–19 pandemic. However, many commenters expressed concern regarding the payment amount in the proposed payment policy for the FY 2022 SNF VBP Program Year. Several commenters recommended that we not reduce each eligible SNF's adjusted Federal per diem rate by 2 percent, or that we return all of the 2 percent withhold to eligible SNFs. Several commenters also noted that if we must proceed with returning only a portion of the 2 percent withhold, we should return 70 percent of the 2 percent withhold rather than 60 percent and that this approach would be reasonable and the most fair given that all providers will be awarded the same incentive payment multiplier and because we are not basing distribution on performance. One commenter recommended that CMS pause the application of SNF incentive payment adjustments for performance years impacted by the PHE.

Response: Though we acknowledge that the COVID–19 PHE has had unprecedented impacts on SNFs, we believe maintaining the 60 percent payback percentage will best provide for the stability and sustainability of the Medicare Program, as well as the stability and sustainability of other

programs funded by the Medicare Trust Fund. Increasing the payback percentage to 70 percent would lead to higher SNF PPS baseline spending that would lower the estimated savings realized by the Medicare Trust Fund in FY 2022 by 19 percent. Specifically, we estimate that increasing the payback percentage to 70 percent would reduce estimated savings from $191.64 million to $154.85 million for that fiscal year. We note that the SNF VBP Program was designed to be a cost-saving program for Medicare. We refer readers to the FY 2018 SNF PPS final rule (82 FR 36619 through 36621) for a discussion of the factors we considered when we specified the 60 percent payback percentage, including a balance between the number of SNFs that receive a positive payment adjustment, the marginal incentives for all SNFs to reduce hospital readmissions and make broad-based care quality improvements, and the Medicare Program's long-term sustainability.

Regarding the recommendation to pause the application of SNF incentive payment adjustments for all performance years impacted by the PHE, we believe that the updated FY 2022 performance period that we adopted in the September 2nd IFC and are finalizing in this final rule, as well as the measure suppression and special scoring and payment policies we are finalizing in this final rule, serve to mitigate the impact of the PHE on SNF VBP performance scores for the FY 2022. Therefore, we do not believe further actions to the SNF VBP Program's incentive payment adjustments would be beneficial to the program at this time. We are continuing to analyze data that may impact the FY 2023 Program.

Comment: One commenter specifically noted that this proposal to reduce each eligible SNF's adjusted Federal per diem rate by the applicable 2 percent and then adjust the resulting amounts by a value-based incentive payment amount equal to 60 percent of the total reduction ''disconnects payment from quality,'' and risks ''rewarding bad actors and penalizing good performers.''

Response: We do not believe that assessing SNFs on a quality measure affected significantly by the varied regional response to the COVID–19 PHE presents a clear picture of the quality of care provided by an individual SNF. Facility-level morbidity and mortality data have been shown to be significantly and disproportionately affected by COVID–19 due to changes in SNF patient case-mix. We are concerned that making payment incentive adjustments using the scoring and payment methodologies specified at § 413.338(c) and (d) could unintentionally award payment incentives to SNFs whose high performance was driven by one or more COVID–19 related factors, such as low COVID–19 prevalence in their locale, lower SNF admissions because of changes in health care patterns, or higher rates of mortality because of conditions related to COVID–19, rather than due to better performance.

Comment: One commenter encouraged CMS to consider modifications to statutory language for situations such as the PHE due to COVID–19 where the Administration could hold participating SNFs harmless.

Response: We thank the commenter for its suggestion and we will take it under consideration.

Comment: One commenter suggested that in addition to the policy we proposed, we should also exclude COVID–19 diagnosed patients from the eligible case count, which would lead to additional SNFs having insufficient numbers of cases and thus receiving a low-volume adjustment rather than a penalty. One commenter questioned whether the 25 or more eligible stay requirement for applying the low-volume adjustment policy is appropriate given the impacts of COVID–19 on SNF residents and facilities and suggested that CMS eliminate all payment cuts for FY 2022.

Response: We do not agree with the commenter's suggestion to exclude COVID–19 diagnosed patients from the SNFRM eligible case count for the FY 2022 program year. As explained above, we believe that our proposal to suppress the SNFRM for FY 2022 scoring and payment adjustment purposes appropriately mitigates the effects of the PHE due to COVID–19. Additionally, excluding COVID–19 diagnosed patients from the eligible case count would negatively affect the Program's impact on the Medicare Trust Fund because it would increase the number of SNFs eligible for the Low-Volume Adjustment policy who receive a net-neutral incentive payment multiplier.

As further detailed below, we believe that the minimum of 25 eligible stays for the performance period as a threshold for applying the Low-Volume Adjustment policy is appropriate and important to maintain for FY 2022, even though we are suppressing the SNFRM measure for scoring and payment adjustment purposes. As noted previously, eliminating all payment cuts for the FY 2022 program year would threaten the stability and maintenance of the SNF VBP Program. We note that while this program is designed to be a cost-savings program, during the COVID–19 PHE, smaller SNFs (those with 45 or fewer eligible stays) and a disproportionate number of rural SNFs have been more vulnerable to unexpected changes in payment or policy as compared to larger SNFs. For the FY 2022 program, we are seeking in particular to protect small and rural SNFs from unexpected or adverse impacts of policies and not applying the LVA would result in those SNFs receiving a deduction when they otherwise would not have. Specifically, when we estimated the impact of the LVA in the upcoming FY 2022 program year, we found that, overall 28 percent of SNFs qualified for the LVA (including 43 percent of all rural SNFs and only 22 percent of all urban SNFs). In comparison to a standard program year, 17 percent of all SNFs would receive the LVA (28.2 percent rural and 12.8 percent urban).

After considering the public comments, we are finalizing our proposed special payment policy for the FY 2022 program year as proposed and codifying it at § 413.338(g) of our regulations.

G. Public Reporting on the Nursing Home Compare Website or a Successor Website

1. Background

Section 1888(g)(6) of the Act requires the Secretary to establish procedures to make SNFs' performance information on SNF VBP Program measures available to the public on the Nursing Home Compare website or a successor website, and to provide SNFs an opportunity to review and submit corrections to that information prior to its publication. We began publishing SNFs' performance information on the SNFRM in accordance with this directive and the statutory deadline of October 1, 2017. In December 2020, we retired the Nursing Home Compare website and are now using the Provider Data Catalogue website (*https://data.cms.gov/provider-data/*) to make quality data available to the public, including SNF VBP performance information.

Additionally, section 1888(h)(9)(A) of the Act requires the Secretary to make available to the public certain information on SNFs' performance under the SNF VBP Program, including SNF performance scores and their ranking. Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the Program, including the range of SNF performance scores and the number of SNFs receiving value-based incentive payments, and

the range and total amount of those payments.

In the FY 2017 SNF PPS final rule (81 FR 52009), we discussed the statutory requirements governing public reporting of SNFs' performance information under the SNF VBP Program. In the FY 2018 SNF PPS final rule (82 FR 36622 through 36623), we finalized our policy to publish SNF VBP Program performance information on the Nursing Home Compare or successor website after SNFs have had an opportunity to review and submit corrections to that information under the two-phase Review and Correction process that we adopted in the FY 2017 SNF PPS final rule (81 FR 52007 through 52009) and for which we adopted additional requirements in the FY 2018 SNF PPS final rule. In the FY 2018 SNF PPS final rule, we also adopted requirements to rank SNFs and adopted data elements that we will include in the ranking to provide consumers and stakeholders with the necessary information to evaluate SNFs' performance under the Program (82 FR 36623).

As discussed in section VIII.B.2. of this final rule, we are finalizing the suppression of the SNFRM for the FY 2022 program year due to the impacts of the PHE for COVID–19. Under this finalized proposal, for all SNFs participating in the FY 2022 SNF VBP Program, we will use the performance period we adopted in the September 2nd IFC and are finalizing in this final rule, as well as the previously finalized baseline period to calculate each SNF's RSRR for the SNFRM. We are also finalizing our proposal to assign all SNFs a performance score of zero. This will result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. Further, we are finalizing our proposal to apply the Low-Volume Adjustment policy as previously finalized in the FY 2019 SNF PPS final rule (83 FR 39278 through 39280). That is, if a SNF has fewer than 25 eligible stays during the performance period for a program year, we will assign that SNF a performance score resulting in a net-neutral payment incentive multiplier.

While we will publicly report the SNFRM rates for the FY 2022 program year, we will make clear in the public presentation of those data that we are suppressing the use of those data for purposes of scoring and payment adjustments in the FY 2022 SNF VBP Program given the significant changes in SNF patient case volume and facility-level case mix described above. Under our finalized policy, SNFs will not be ranked for the FY 2022 SNF VBP Program.

2. Data Suppression Policy for Low-Volume SNFs

In the FY 2020 SNF PPS final rule (84 FR 38823 through 38824), we adopted a data suppression policy for low-volume SNF performance information. Specifically, we finalized that we will suppress the SNF performance information available to display as follows: (1) If a SNF has fewer than 25 eligible stays during the baseline period for a program year, we will not display the baseline risk-standardized readmission rate (RSRR) or improvement score, although we will still display the performance period RSRR, achievement score, and total performance score if the SNF had sufficient data during the performance period; (2) if a SNF has fewer than 25 eligible stays during the performance period for a program year and receives an assigned SNF performance score as a result, we will report the assigned SNF performance score and we will not display the performance period RSRR, the achievement score, or improvement score; and (3) if a SNF has zero eligible cases during the performance period for a program year, we will not display any information for that SNF. We codified this policy in the FY 2021 SNF PPS final rule (85 FR 47626) at § 413.338(e)(3)(i), (ii), and (iii).

As discussed in section VIII.B.2. of this final rule, we are finalizing the suppression of the SNFRM for the FY 2022 program year and our proposals for scoring and payment in FY 2022, including applying the Low-Volume Adjustment policy as previously finalized. That is, if a SNF has fewer than 25 eligible stays during the performance period for FY 2022 (April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020), we will assign that SNF a performance score resulting in a net-neutral payment incentive multiplier.

3. Public Reporting of SNF VBP Performance Information on Nursing Home Compare or a Successor Website

Section 1888(h)(9)(A) of the Act requires that the Secretary make available to the public on the Nursing Home Compare website or a successor website information regarding the performance of individual SNFs for a fiscal year, including the performance score for each SNF for the fiscal year and each SNF's ranking, as determined under section 1888(h)(4)(B) of the Act. Additionally, section 1888(h)(9)(B) of the Act requires that the Secretary periodically post aggregate information on the SNF VBP Program on the Nursing Home Compare website or a successor website, including the range of SNF performance scores, and the number of SNFs receiving value-based incentive payments and the range and total amount of those payments. In the FY 2018 SNF PPS final rule (82 FR 36622 through 36623), we finalized our policy to publish SNF measure performance information under the SNF VBP Program on Nursing Home Compare.

In the FY 2021 SNF PPS final rule (85 FR 47626), we finalized an amendment to § 413.338(e)(3) to reflect that we will publicly report SNF performance information on the Nursing Home Compare website or a successor website located at *https://data.cms.gov/provider-data//*. We did not propose any changes to the public reporting policies in the proposed rule.

H. Update and Codification of the Phase One Review and Correction Claims ''Snapshot'' Policy

In the FY 2017 SNF PPS final rule (81 FR 52007 through 52009), we adopted a two-phase review and corrections process for SNFs' quality measure data that will be made public under section 1888(g)(6) of the Act and SNF performance information that will be made public under section 1888(h)(9) of the Act. We detailed the process for requesting Phase One corrections and finalized a policy whereby we would accept Phase One corrections to a quarterly report provided during a calendar year until the following March 31.

In the FY 2020 SNF PPS final rule (84 FR 38824 through 38835), we updated this policy to reflect a 30-day Phase One Review and Correction deadline rather than through March 31st following receipt of the performance period quality measure quarterly report.

In the FY 2021 SNF PPS final rule (85 FR 47626 through 47627), we updated the 30-day deadline for Phase One Review and Correction and codified the policy at § 413.338(e)(1). Under the updated policy, beginning with the baseline period quality report issued on or after October 1, 2020 that contains the baseline period measure rate and underlying claim information used to calculate the measure rate for the applicable program year, SNFs have 30 days following the date that CMS provides those reports to review and submit corrections to the data contained in those reports. We also stated that if the issuance dates of these reports are significantly delayed or need to be shifted for any reason, we would notify SNFs through routine communication channels including, but not limited to

memos, emails, and notices on the CMS SNF VBP website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/SNF-VBP-Page.*

We proposed to include a Phase One Review and Correction claims ''snapshot'' policy beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021. This proposed policy would limit the Phase One Review and Correction to errors made by CMS or its contractors when calculating a SNF's readmission measure rate and would not allow corrections to the underlying administrative claims data used to calculate those rates. Under this proposed policy, the administrative claims data we use to calculate a SNF's readmission measure rate for purposes of a baseline period or performance period for a given SNF VBP Program Year would be held constant (that is, frozen in a ''snapshot'') from the time we extract it for that purpose. This proposal would align the review and correction policy for the SNF VBP Program with the review and correction policy we have adopted for other value-based purchasing programs, including the Hospital Readmissions Reduction Program (HRRP), Hospital-Acquired Condition (HAC) Reduction Program, and Hospital VBP Program.

For purposes of this program, we proposed to calculate the SNF readmission measure rates using a static ''snapshot'' of claims updated as of 3 months following the last index SNF admission in the applicable baseline period or performance period. The source of the administrative claims data we use to calculate the SNF readmission measure is the Medicare Provider Analysis and Review (MedPAR). For example, if the last index SNF admission date for the applicable baseline period or performance period is September 30, 2019, we would extract the administrative claims data from the MedPAR file as that data exists on December 31, 2019. SNFs would then receive their SNF readmission measure rate and accompanying stay-level information in their confidential quality measure quarterly reports, and they would have an opportunity to review and submit corrections to our calculations as part of the Phase One corrections process. However, SNFs would not be able to correct any of the underlying administrative claims data (for example, a SNF discharge destination code) we use to generate the measure rate.

The use of a data ''snapshot'' enables us to provide as timely quality data as possible, both to SNFs for the purpose of quality improvement and to the public for the purpose of transparency. After the claims ''snapshot'' is taken through our extraction of the data from MedPAR, it takes several months to incorporate other data needed for the SNF readmission measure calculations, generate and check the calculations, as well as program, populate, and deliver the confidential quarterly reports and accompanying data to SNFs. Because several months lead-time is necessary after acquiring the input data to generate these calculations, if we were to delay our data extraction point beyond the date that is 3 months after the last SNF index admission attributable to a baseline period or performance period, we believe this would create an unacceptably long delay both for SNFs to receive timely data for quality improvement and transparency, and, incentive payments for purposes of this program. Therefore, we believe that a 3-month claims ''run-out'' period between the date of the last SNF index admission and the date of the data extraction is a reasonable period that allows SNFs time to correct their administrative claims or add any missing claims before those claims are used for measure calculation purposes while enabling us to timely calculate the measure. If unforeseen circumstances require the use of additional months of claims ''run-out'', that is, more than 3 months, we would notify SNFs through routine communication channels including, but not limited to, memos, emails, quarterly reports and notices on the CMS SNF VBP website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/SNF-VBP-Page.*

We believe this proposed policy would address both fairness and operational concerns associated with calculating measure rates and would provide consistency across value-based purchasing programs.

We also proposed to codify this policy in our regulations by revising § 413.338(e)(1) to remove the policies that would no longer be applicable beginning October 1, 2021 and state the newly proposed policy that would be effective, if finalized, on October 1, 2021.

We invited public comment on this proposal to update the Phase One Review and Correction policy.

The following is a summary of the public comments received on our proposal to Update and Codify the Phase One Review and Correction Claims ''Snapshot'' Policy and our responses:

Comment: A few commenters supported updating the Phase One Review and Corrections policy to align with the review and corrections policy in other value-based purchasing programs.

Response: We thank the commenters for their support.

After considering the comments, we are finalizing the updated Phase One Review and Corrections claims ''snapshot'' policy as proposed and codifying it at § 413.338(e)(1) of our regulations.

I. Update to the Instructions for Requesting an ECE in § 413.338(d)(4)(ii) of the SNF VBP Regulations

We proposed to update the instructions for a SNF to request an extraordinary circumstances exception (ECE). Specifically, we proposed to update the URL for our QualityNet website from *QualityNet.org* to *QualityNet.cms.gov.* We also proposed to update the email address that a SNF must use to send an ECE request. We also proposed to remove the separate reference to newspapers because newspapers are already included in the broader term ''media articles.'' We proposed to update § 413.338(d)(4)(ii) of our regulations to reflect these changes.

We invited public comment on this proposal.

The following is a summary of the public comments received on our proposal to Update the Instructions for Requesting an ECE in § 413.338(d)(4)(ii) of the SNF VBP Regulations and our responses:

Comment: A few commenters supported our proposal to update the instructions to request an ECE in the SNF VBP regulations.

Response: We thank these commenters for their support.

After considering the public comments, we are finalizing our proposal to update the instructions for requesting an ECE in the SNF VBP regulations and codifying it at § 413.338(d)(4)(ii) of our regulations. However, due to operational concerns, we are updating the regulation text to specify that a SNF may request an exception in the form and manner specified by CMS on the SNF VBP website, which will include the appropriate email address to which a SNF can send its ECE request.

IX. Technical Correction for § 483.90(d)

In the July 18, 2019 ''Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Efficiency, and

Transparency'' proposed rule, we proposed a technical correction to revise § 483.90(d)(1) and add paragraph (d)(3) to correct an error in the Code of Federal Regulations (CFR) (84 FR 34737).

Previously, on July 13, 2017, we issued a correcting amendment entitled, ''Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities'' correcting amendment (82 FR 32256) to correct technical and typographical errors identified in the October 2016 ''Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities'' final rule (81 FR 68688). This document inadvertently removed revisions made to § 483.90(d), which were finalized in the October 2016 final rule. Specifically, the rule finalized requirements at § 483.90(d) (incorrectly labeled paragraph (c) in the October 2016 final rule) for facilities to—(1) provide sufficient space and equipment in dining, health services, recreation, living, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's assessment and plan of care at § 483.90(d)(1)); (2) maintain all mechanical, electrical, and patient care equipment in safe operating condition at § 483.90(d)(2); and (3) conduct regular inspection of all bed frames, mattresses, and bed rails, if any, as part of a regular maintenance program to identify areas of possible entrapment. When bed rails and mattresses are used and purchased separately from the bed frame, the facility must ensure that the bed rails, mattress, and bed frame are compatible at § 483.90(d)(3).

We did not receive comments in response to this proposal. Therefore, we are finalizing this technical correction, as proposed, to revise § 483.90(d)(1) and add paragraph (d)(3).

X. Collection of Information Requirements

Consistent with our April 15, 2021 (86 FR 19954) proposed rule, this final rule will not impose any new or revised ''collection of information'' requirements or burden as it pertains to CMS. For the purpose of this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the Paperwork Reduction Act of 1995's (PRA) (44 U.S.C. 3501 *et seq.*) implementing regulations. Consequently, this rule is not subject to the requirements of the PRA.

In section VII.C.1. of this final rule, we are finalizing the adoption of the SNF HAIs Requiring Hospitalization measure beginning with the FY 2023 SNF QRP. The measure is claims-based. All claims-based measures are calculated using data that are already reported to the Medicare program for payment purposes. Since the data source for this measure is Medicare fee-for-service claims, there is no additional burden for SNFs.

In section VII.C.2. of this final rule, we are finalizing the adoption of the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2023 SNF QRP. SNFs must submit data on the measure through the CDC/National Healthcare Safety Network (NHSN). We note that the CDC will account for the burden associated with the COVID–19 Vaccination Coverage among HCP measure collection under OMB control number 0920–1317 (current expiration January 31, 2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660, enacted on November 14, 1986) (NCVIA).[118] We refer readers to section XI.A.5. of this final rule for an estimate of the burden to SNFs, and note that the CDC will include it in a revised information collection request under said control number.

In section VII.C.3. of this final rule, we are finalizing our proposal to update the Transfer of Health (TOH) Information to the Patient—Post Acute Care (PAC) measure to exclude residents discharged home under the care of an organized home health service or hospice. This measure was adopted in the FY 2020 SNF PPS final rule (84 FR 38728) and the associated burden was accounted for under OMB control number 0938–1140 (CMS–10387) (current expiration November 30, 2022). The update will not affect the requirements and burden that are currently approved under that control number.

In section VII.G.3. of this final rule, we are finalizing our proposal that SNFs submit data on the COVID–19 Vaccination among HCP measure through the CDC/National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based surveillance system that is maintained by the CDC and provided free of charge to healthcare facilities including SNFs.

While the NHSN is currently not utilized by SNFs for purposes of meeting the SNF QRP requirements, nursing homes were enrolled in the NHSN in 2020 and are currently submitting mandatory COVID–19 data through the Long-term Care Facility COVID–19 module (*https://www.cdc.gov/nhsn/ltc/covid19/index.html*). As such, there is no additional information collection burden related to the onboarding and training of SNF providers to utilize this system.

In section VIII.B.2. of this final rule, we are finalizing our proposal to suppress the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) for scoring and payment purposes for the FY 2022 SNF VBP Program Year. Because the data source for this quality measure is Medicare fee-for-service claims, there is no additional burden for SNFs. All claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes.

XI. Economic Analyses

A. Regulatory Impact Analysis

1. Statement of Need

This final rule updates the FY 2022 SNF prospective payment rates as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted Federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. As these statutory provisions prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, we do not have the discretion to adopt an alternative approach on these issues.

2. Introduction

We have examined the impacts of this final rule 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 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), and the Congressional Review Act (5 U.S.C. 804(2)).

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

[118] Section 321 of the NCVIA provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

(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 rule has been designated an economically significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis (RIA) as further discussed below. Also, the rule has been reviewed by OMB.

3. Overall Impacts

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2021 (85 FR 47594). We estimate that the aggregate impact would be an increase of approximately $410 million in Part A payments to SNFs in FY 2022. This reflects a $411 million increase from the update to the payment rates and a $1.2 million decrease due to the proposed reduction to the SNF PPS rates to account for the recently excluded blood-clotting factors (and items and services related to the furnishing of such factors) in section 1888(e)(2)(A)(iii)(VI) of the Act. We note that these impact numbers do not incorporate the SNF VBP Program reductions that we estimate would total $191.64 million in FY 2022. We would note that events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented, and thus, very susceptible to forecasting errors due to events that may occur within the assessed impact time period.

In accordance with sections 1888(e)(4)(E) and (e)(5) of the Act and implementing regulations at § 413.337(d), we are updating the FY 2021 payment rates by a factor equal to the market basket index percentage change reduced by the forecast error adjustment and the productivity adjustment to determine the payment rates for FY 2022. The impact to Medicare is included in the total column of Table 32. When proposing the SNF PPS rates for FY 2022, we proposed a number of standard annual revisions and clarifications mentioned elsewhere in this final rule (for example, the proposed update to the wage and market basket indexes used for adjusting the Federal rates).

The annual update in this rule applies to SNF PPS payments in FY 2022. Accordingly, the analysis of the impact of the annual update that follows only describes the impact of this single year. Furthermore, in accordance with the requirements of the Act, we will publish a rule or notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2022 SNF PPS payment impacts appear in Table 32. Using the most recently available data, in this case FY 2020, we apply the current FY 2021 CMIs, wage index and labor-related share value to the number of payment days to simulate FY 2021 payments. Then, using the same FY 2020 data, we apply the FY 2022 CMIs, wage index and labor-related share value to simulate FY 2022 payments. We would note that, given that this same data is being used for both parts of this calculation, as compared to other analyses discussed in this final rule which compare data from FY 2020 to data from other fiscal years, any issues discussed throughout this final rule with regard to data collected in FY 2020 will not cause any difference in this economic analysis. We tabulate the resulting payments according to the classifications in Table 32 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2021 payments to the simulated FY 2022 payments to determine the overall impact. The breakdown of the various categories of data in Table 32 follows:

- The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.
- The first row of figures describes the estimated effects of the various proposed changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).
- The second column shows the number of facilities in the impact database.
- The third column shows the effect of the proposed annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is 0.0 percent; however, there are distributional effects of the proposed change.
- The fourth column shows the effect of all of the changes on the FY 2022 payments. The update of 1.2 percent is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments would increase by 1.2 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 32, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes in this final rule, rural providers would experience a 1.6 percent increase in FY 2022 total payments. Finally, we note that we did not include in Table 32 the distributional impacts associated with the blood-clotting factor exclusion because the reduction is so minor that it does not have any visible effect on the distributional impacts included in the Table 32.

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TABLE 32: Impact to the SNF PPS for FY 2022

Provider Characteristics	# Providers	Update Wage Data	Total Change
Group			
Total	15,560	0.0%	1.2%
Urban	10,962	-0.1%	1.1%
Rural	4,598	0.4%	1.6%
Hospital-based urban	401	-0.1%	1.1%
Freestanding urban	10,561	-0.1%	1.1%
Hospital-based rural	466	0.4%	1.6%
Freestanding rural	4,132	0.4%	1.6%
Urban by region			
New England	744	-0.7%	0.5%
Middle Atlantic	1,456	-0.5%	0.7%
South Atlantic	1,834	0.3%	1.5%
East North Central	2,160	-0.2%	1.0%
East South Central	542	-0.1%	1.1%
West North Central	924	0.3%	1.5%
West South Central	1,363	-0.2%	0.9%
Mountain	539	0.2%	1.4%
Pacific	1,394	0.2%	1.4%
Outlying	6	0.4%	1.6%
Rural by region			
New England	130	-1.0%	0.2%
Middle Atlantic	246	0.6%	1.8%
South Atlantic	604	1.4%	2.6%
East North Central	921	0.5%	1.7%
East South Central	528	0.0%	1.2%
West North Central	1,064	-0.4%	0.8%
West South Central	769	0.3%	1.5%
Mountain	224	0.5%	1.7%
Pacific	112	0.2%	1.4%
Ownership			
For profit	10866	0.0%	1.2%
Non-profit	3,687	0.0%	1.2%
Government	1,007	0.1%	1.3%

Note: The Total column includes the FY 2022 1.2 percent market basket update factor. Additionally, we found no SNFs in rural outlying areas.

5. Impacts for the SNF QRP for FY 2022

Estimated impacts for the SNF QRP are based on analysis discussed in section IX.B. of this final rule. The SNF QRP requirements add no additional burden to the active collection under OMB control number #0938–1140 (CMS–10387; expiration November 30, 2022).

In accordance with section 1888(e)(6)(A)(i) of the Act, the Secretary must reduce by 2 percentage points the annual payment update applicable to a SNF for a fiscal year if the SNF does not comply with the requirements of the SNF QRP for that fiscal year. In section VII.A. of this final rule, we discuss the method for applying the 2 percentage point reduction to SNFs that fail to meet the SNF QRP requirements. As discussed in section VII.C. of this final rule, we are finalizing the adoption of two new measures to the SNF QRP beginning with the FY 2023 SNF QRP: SNF Healthcare-Associated Infections Requiring Hospitalization Measure (SNF–HAI) and the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure. The SNF–HAI measure is a claims-based measure, and therefore, would impose no additional burden to the SNFs.

We believe that the burden associated with the SNF QRP is the time and effort associated with complying with the non-claims-based measures requirements of the SNF QRP. Although the burden associated with the COVID–19 Vaccination Coverage among HCP measure is not accounted for under the CDC PRA package currently approved under OMB control number 0920–1317 due to the NCVIA waiver the cost and burden is discussed here and will be included in a revised information collection request for 0920–1317.

Consistent with the CDC's experience of collecting data using the NHSN, we estimate that it would take each SNF an average of 1 hour per month to collect data for the COVID–19 Vaccination

Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. We believe it would take an administrative assistant from 45 minutes up to 1 hour and 15 minutes to enter this data into NHSN. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates.[119] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 33.

TABLE 33: U.S. Bureau of Labor and Statistics' May 2019 National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean Hourly Wage ($/hr)	Overhead and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Administrative Assistant	43-6013	$18.31	$18.31	$36.62

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Based on this time range, it would cost each SNF between $27.47 and $45.78 each month or an average cost of $36.62 each month, and between $329.64 and $549.36 each year, or an average cost of $439.44 each year. We believe the data submission for the COVID–19 Vaccination Coverage among HCP measure would cause SNFs to incur additional average burden of 12 hours per year for each SNF and a total annual burden of 180,936 hours for all SNFs. The estimated annual cost across all 15,078 SNFs in the U.S. for the submission of the COVID–19 Vaccination Coverage among HCP measure would be between $4,970,312 and $8,283,250.08, and an average of $6,625,872.

We recognize that many SNFs may also be reporting other COVID–19 data to HHS. However, we believe the benefits of reporting data on the COVID–19 Vaccination Coverage among HCP measure to assess whether SNFs are taking steps to limit the spread of COVID–19 among their HCP, reduce the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of SNFs to continue serving their communities throughout the PHE and beyond outweigh the costs of reporting. We welcomed comments on the estimated time to collect data and enter it into NHSN.

We did not receive any comments on the estimated time to collect data and enter it into NHSN, and are finalizing the revisions as proposed.

6. Impacts for the SNF VBP Program

The estimated impacts of the FY 2022 SNF VBP Program are based on historical data from February 1, 2019 to September 30, 2019. In section VIII.B.2. of this final rule, we discuss the suppression of the SNFRM for the FY 2022 program year. As finalized, we will award each participating SNF 60 percent of their 2 percent withhold, except those SNFs subject to the low-volume scoring adjustment, which would each receive 100 percent of their 2 percent withhold. We estimated that the low-volume scoring adjustment would increase the 60 percent payback percentage for FY 2022 by approximately 2.9 percentage points (or $14.8 million), resulting in a payback percentage for FY 2022 that is 62.9 percent of the estimated $516.2 million in withheld funds for that fiscal year. Based on the 60 percent payback percentage (as modified by the low-volume scoring adjustment), we estimated that we will redistribute approximately $324.5 million in value-based incentive payments to SNFs in FY 2022, which means that the SNF VBP Program is estimated to result in approximately $191.6 million in savings to the Medicare Program in FY 2022.

7. Impacts for Long Term Care Facilities: Physical Environment Requirements Technical Correction

There are no impacts associated with this technical correction.

8. Alternatives Considered

As described in this section, we estimated that the aggregate impact for FY 2022 under the SNF PPS would be an increase of approximately $410 million in Part A payments to SNFs. This reflects a $411 million increase from the update to the payment rates, and a $1.2 million decrease due to the proposed reduction to the SNF PPS rates to account for the recently excluded blood-clotting factors (and items and services related to the furnishing of such factors) in section 1888(e)(2)(A)(iii)(VI) of the Act.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating base payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the Federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY; accordingly, we are not pursuing alternatives for this process.

With regard to the alternatives considered related to the other provisions contained in this final rule, such as the methodology for calculating the proportional reduction to the rates to account for the exclusion of blood clotting factors from SNF consolidated billing, we discuss any alternatives considered within those sections.

With regard to the SNF VBP Program measure suppression policy, we discuss alternatives considered within those sections.

9. Accounting Statement

As required by OMB Circular A–4 (available online at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Tables 34, 35, and 36, we have prepared an accounting

[119] *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed on March 30, 2021.

statement showing the classification of the expenditures associated with the provisions of this final rule for FY 2022. Tables 32 and 34 provide our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this final rule, based on the data for 15,560 SNFs in our database. Table 35 provides our best estimate of the possible changes in Medicare payments under the SNF VBP as a result of the policies we have proposed for this program. Tables 33 and 36 provide our best estimate of the additional cost to SNFs to submit the data for the SNF QRP as a result of the policies in this final rule.

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TABLE 34: Accounting Statement: Classification of Estimated Expenditures, from the 2021 SNF PPS Fiscal Year to the 2022 SNF PPS Fiscal Year

Category	Transfers
Annualized Monetized Transfers	$410 million*
From Whom To Whom?	Federal Government to SNF Medicare Providers

* The net increase of $410 million in transfer payments is a result of the $411 million increase due to the market basket update factor of 1.2 percent, reduced by $1.2 million due to the proportional reduction associated with excluding blood clotting factors from SNF consolidated billing.

TABLE 35: Accounting Statement: Classification of Estimated Expenditures for the FY 2022 SNF VBP Program

Category	Transfers
Annualized Monetized Transfers	$324.5 million*
From Whom To Whom?	Federal Government to SNF Medicare Providers

*This estimate does not include the 2 percent reduction to SNFs' Medicare payments (estimated to be $516.15 million) required by statute.

TABLE 36: Accounting Statement: Classification of Estimated Expenditures for the FY 2022 SNF QRP Program

Category	Transfers/Costs
Costs for SNFs to Submit Data for QRP	$6.6 million*

*Costs associated with the submission of data for the COVID-19 Vaccination Coverage among HCP will occur in FY 2022 and is likely to continue in future years.

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10. Conclusion

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2021 (85 FR 47594). Based on the above, we estimate that the overall payments for SNFs under the SNF PPS in FY 2022 are projected to increase by approximately $410 million, or 1.2 percent, compared with those in FY 2021. We estimate that in FY 2022, SNFs in urban and rural areas would experience, on average, a 1.1 percent increase and 1.0036 percent increase, respectively, in estimated payments compared with FY 2021. Providers in the rural South Atlantic region would experience the largest estimated increase in payments of approximately 2.6 percent. Providers in the rural New England region would experience the smallest estimated increase in payments of 0.2 percent.

B. Regulatory Flexibility Act 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, small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $30 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, for the purposes of the RFA, we estimate that almost all SNFs are small entities as that term is used in the RFA, according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $30 million or less in any 1 year. (For details, see the Small Business Administration's website at *http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*). In addition, approximately 20 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This rule would update the SNF PPS rates contained in the SNF PPS final

rule for FY 2021 (85 FR 47594). Based on the above, we estimate that the aggregate impact for FY 2022 would be an increase of $410 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, reduced by the impact of excluding blood clotting factors (and items and services related to the furnishing of such factors) from SNF consolidated billing under section 1888(e)(2)(A)(iii)(VI) and (e)(4)(G)(iii) of the Act. While it is projected in Table 32 that all providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2022 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. In their March 2021 Report to Congress (available at *http://www.medpac.gov/docs/default-source/reports/mar21_medpac_ch7_sec.pdf*), MedPAC states that Medicare covers approximately 9 percent of total patient days in freestanding facilities and 16 percent of facility revenue (March 2020 MedPAC Report to Congress, 224). As indicated in Table 32, the effect on facilities is projected to be an aggregate positive impact of 1.2 percent for FY 2022. As the overall impact on the industry as a whole, and thus on small entities specifically, is less than the 3 to 5 percent threshold discussed previously, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities for FY 2022.

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 604 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 an MSA and has fewer than 100 beds. This final rule will affect small rural hospitals that: (1) Furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals will be a positive impact. Moreover, as noted in previous SNF PPS final rules (most recently, the one for FY 2021 (85 FR 47594)), the category of small rural hospitals is included within the analysis of the impact of this final rule on small entities in general. As indicated in Table 32, the effect on facilities for FY 2022 is projected to be an aggregate positive impact of 1.2 percent. As the overall impact on the industry as a whole is less than the 3 to 5 percent threshold discussed above, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small rural hospitals for FY 2022.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 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. In 2021, that threshold is approximately $158 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule will have no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

F. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final 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 the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons, we believe that the number of commenters on this year's proposed rule is a fair estimate of the number of reviewers of this final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the national mean hourly wage data from the May 2020 BLS Occupational Employment Statistics (OES) for medical and health service managers (SOC 11–9111), we estimate that the cost of reviewing this rule is $114.24 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 would take approximately 4 hours for the staff to review half of the proposed rule. For each SNF that reviews the rule, the estimated cost is $456.96 (4 hours × $114.24). Therefore, we estimate that the total cost of reviewing this regulation is $156,280.32 ($442.96 × 342 reviewers).

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

I, Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 21, 2021.

List of Subjects

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 413

Principles of reasonable cost reimbursement; payment for end-stage renal disease services; optional prospectively determined payment rates for skilled nursing facilities; payment for acute kidney injury dialysis.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 2. Amend § 411.15 by—
■ a. Revising paragraphs (p)(2)(xiii) through (xvi);
■ b. Redesignating paragraph (p)(2)(xvii) as (p)(2)(xviii); and
■ c. Adding new paragraph (p)(2)(xvii).

The revisions and addition read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(p) * * *

(2) * * *

(xiii) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020, J9040–J9151, J9170–J9185, J9200–J9201, J9206–J9208, J9211, J9230–J9245, and J9265–J9600, and as of January 1, 2004, by HCPCS codes A9522, A9523, A9533, and A9534 (as subsequently modified by CMS), and any additional chemotherapy items identified by CMS.

(xiv) Those chemotherapy administration services identified, as of July 1, 1999, by HCPCS codes 36260–36262, 36489, 36530–36535, 36640, 36823, and 96405–96542 (as subsequently modified by CMS), and any additional chemotherapy administration services identified by CMS.

(xv) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440 (as subsequently modified by CMS), and any additional radioisotope services identified by CMS.

(xvi) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999, by HCPCS codes L5050–L5340, L5500–L5611, L5613–L5986, L5988, L6050–L6370, L6400–6880, L6920–L7274, and L7362–L7366 (as subsequently modified by CMS) and any additional customized prosthetic devices identified by CMS, which are delivered for a resident's use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

(xvii) Those blood clotting factors indicated for the treatment of patients with hemophilia and other bleeding disorders identified, as of July 1, 2020, by HCPCS codes J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211 (as subsequently modified by CMS) and items and services related to the furnishing of such factors, and any additional blood clotting factors identified by CMS and items and services related to the furnishing of such factors.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 3. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 4. Amend § 413.338 by revising paragraphs (d)(4)(ii) and (e)(1) and adding paragraph (g) to read as follows:

§ 413.338 Skilled nursing facility value-based purchasing program.

* * * * *

(d) * * *

(4) * * *

(ii) A SNF may request an exception within 90 days of the date that the extraordinary circumstances occurred in the form and manner specified by CMS on the SNF VBP website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/Extraordinary-Circumstance-Exception-*. The request must include a completed Extraordinary Circumstances Request form (available on *https://qualitynet.cms.gov/*) and any available evidence of the impact of the extraordinary circumstances on the care that the SNF furnished to patients including, but not limited to, photographs and media articles.

* * * * *

(e) * * *

(1) CMS will provide quarterly confidential feedback reports to SNFs on their performance on the SNF readmission measure. Beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021, which contain the baseline period and performance period measure rates, respectively, SNFs will have 30 days following the date CMS provides each of these reports to review and submit corrections to the SNF readmission measure rates contained in that report. The administrative claims data used to calculate a SNF's readmission measure rates are not subject to review and correction under this paragraph (e)(1). All correction requests must be accompanied by appropriate evidence showing the basis for the correction to the SNF readmission measure rates.

* * * * *

(g) *Special rules for the FY 2022 SNF VBP Program.* (1) CMS will calculate a SNF readmission measure rate for each SNF based on its performance on the SNF readmission measure during the performance period specified by CMS for fiscal year 2022, but CMS will not calculate a performance score for any SNF using the methodology described in paragraphs (d)(1) and (2) of this section. CMS will instead assign a performance score of zero to each SNF, with the exception of those SNFs qualifying for the low-volume scoring adjustment described in paragraph (d)(3) of this section.

(2) CMS will calculate the value-based incentive payment adjustment factor for each SNF using a performance score of zero and will then calculate the value-based incentive payment amount for each SNF using the methodology described in paragraph (c)(2)(ii) of this section. CMS will then apply low-volume scoring adjustment described in paragraph (d)(3) of this section.

(3) CMS will provide confidential feedback reports to SNFs on their performance on the SNF readmission measure in accordance with paragraphs (e)(1) and (2) of this section.

(4) CMS will publicly report SNF performance on the SNF readmission measure in accordance with paragraph (e)(3) of this section.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 5. The authority citation for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r.

■ 6. Amend § 483.90 by revising paragraph (d) to read as follows:

§ 483.90 Physical environment.

* * * * *

(d) *Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, health services, recreation, living, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's assessment and plan of care;

(2) Maintain all mechanical, electrical, and patient care equipment in safe operating condition; and

(3) Conduct regular inspection of all bed frames, mattresses, and bed rails, if any, as part of a regular maintenance program to identify areas of possible entrapment. When bed rails and mattresses are used and purchased separately from the bed frame, the facility must ensure that the bed rails, mattress, and bed frame are compatible.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 7. The authority citation for part 489 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

■ 8. Amend § 489.20 by—

■ a. Revising paragraphs (s)(13) through (16);

■ b. Redesignating paragraph (s)(17) as paragraph (s)(18); and

■ c. Adding new paragraph (s)(17).

The revisions and addition read as follows:

§ 489.20 Basis commitments.

* * * * *

(s) * * *

(13) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020, J9040–J9151, J9170–J9185, J9200–J9201, J9206–J9208, J9211, J9230–J9245, and J9265–J9600, and as of January 1, 2004, by HCPCS codes A9522, A9523, A9533, and A9534 (as subsequently modified by CMS), and any additional chemotherapy items identified by CMS.

(14) Those chemotherapy administration services identified, as of July 1, 1999, by HCPCS codes 36260–36262, 36489, 36530–36535, 36640, 36823, and 96405–96542 (as subsequently modified by CMS), and any additional chemotherapy administration services identified by CMS.

(15) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440 (as subsequently modified by CMS), and any additional radioisotope services identified by CMS.

(16) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999, by HCPCS codes L5050–L5340, L5500–L5611, L5613–L5986, L5988, L6050–L6370, L6400–6880, L6920–L7274, and L7362–L7366 (as subsequently modified by CMS) and any additional customized prosthetic devices identified by CMS, which are delivered for a resident's use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

(17) Those blood clotting factors indicated for the treatment of patients with hemophilia and other bleeding disorders identified, as of July 1, 2020, by HCPCS codes J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211 (as subsequently modified by CMS) and items and services related to the furnishing of such factors, and any additional blood clotting factors identified by CMS and items and services related to the furnishing of such factors.

* * * * *

Dated: July 27, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–16309 Filed 7–29–21; 4:15 pm]

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Part V

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 418

Medicare Program; FY 2022 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice and Home Health Quality Reporting Program Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1754–F]

RIN 0938–AU41

Medicare Program; FY 2022 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice and Home Health Quality Reporting Program Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the hospice wage index, payment rates, and aggregate cap amount for Fiscal Year 2022. This rule makes changes to the labor shares of the hospice payment rates and finalizes clarifying regulations text changes to the election statement addendum that was implemented on October 1, 2020. In addition, this rule makes permanent selected regulatory blanket waivers that were issued to Medicare-participating hospice agencies during the COVID–19 public health emergency (PHE) and updates the hospice conditions of participation. This rule updates the Hospice Quality Reporting Program and finalizes changes beginning with the January 2022 public reporting for the Home Health Quality Reporting Program to address exceptions related to the COVID–19 PHE.

DATES: These regulations are effective on October 1, 2021.

FOR FURTHER INFORMATION CONTACT: For general questions about hospice payment policy, send your inquiry via email to *hospicepolicy@cms.hhs.gov.*

For questions regarding the CAHPS® Hospice Survey, contact Lori Teichman at (410) 786–6684, Lauren Fuentes at (410) 786–2290, and Debra Dean-Whittaker at (410)786–9848.

For questions regarding the hospice conditions of participation, contact Mary Rossi-Coajou at (410) 786–6051 and CAPT James Cowher at (410) 786–1948.

For questions regarding home health public reporting, contact Charles Padgett (410) 786–2811.

For questions regarding the hospice quality reporting program, contact Cindy Massuda at (410) 786–0652.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose

This rule updates the hospice wage index, payment rates, and cap amount for fiscal year (FY) 2022 as required under section 1814(i) of the Social Security Act (the Act). In addition, this rule rebases the labor shares of the hospice payment rates and finalizes clarifying regulations text changes to the election statement addendum requirements finalized in the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38484). This rule also provides a summary of comments received regarding hospice utilization and spending patterns. This rule makes permanent selected regulatory blanket waivers for hospice agencies during the COVID–19 public health emergency (PHE) and provides revisions to the hospice conditions of participation (CoPs). This rule finalizes changes to the Hospice Quality Reporting Program (HQRP), summarizes the comments to the requests for information on advancing to digital quality measurement and the use of Fast Healthcare Interoperability Resources (FHIR) and the White House Executive Order related to health equity in the HQRP. Finally, this rule finalizes changes to the Home Health Quality Reporting Program (HH QRP) to address the January 2022 refresh in accordance with sections 1895(b)(3)(B)(v)(III) and 1899B(f) of the Act.

B. Summary of the Major Provisions

Section III.A of this final rule includes a summary of comments from the public, including hospice providers as well as patients and advocates, regarding the presented analysis in the FY 2022 hospice proposed rule on hospice utilization, spending patterns and non-hospice spending during a hospice election.

Section III.B of this final rule rebases and revises the labor shares for continuous home care (CHC), routine home care (RHC), inpatient respite care (IRC), and general inpatient care (GIP) using 2018 Medicare cost report (MCR) data for freestanding hospice facilities.

Section III.C of this rule updates the hospice wage index and makes the application of the updated wage data budget neutral for all four levels of hospice care and discusses the FY 2022 hospice payment update percentage of 2.0 percent, updates to the hospice payment rates, as well as the updates to the hospice cap amount for FY 2022 by the hospice payment update percentage of 2.0 percent.

Section III.D finalizes clarifying regulations text changes regarding the election statement addendum requirements that were finalized in the FY 2020 Hospice Wage Index and Rate Update final rule (84 FR 38484).

Section III.E makes permanent selected regulatory blanket waivers that were issued to Medicare-participating hospice agencies during the COVID–19 PHE. We are revising the hospice aide requirements to allow the use of the pseudo-patient for conducting hospice aide competency evaluations. We are also revising the hospice aide supervision requirements to address situations when deficient practice is noted and remediation is needed related to both deficient and related skills, in accordance with § 418.76(c).

In section III.F of this rule, we finalize proposals to the HQRP including the addition of claims-based Hospice Care Index (HCI) measure, and Hospice Visits in the Last Days of Life (HVLDL) measure for public reporting; removal of the seven Hospice Item Set (HIS) measures because a more broadly applicable measure, the NQF #3235 HIS Comprehensive Assessment Measure for the particular topic is available and already publicly reported; and further development of the Hospice Outcome and Patient Evaluation (HOPE) assessment instrument. We also finalize the public reporting change for one refresh cycle to report less than the standard quarters of data due to the COVID–19 PHE exemptions; use 2 years (8 quarters) of data for the claims-based measures in order to report on small providers; and add the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey Star ratings. Additionally, we summarize the comments on the requests for information (RFI) on advancing to digital quality measurement and the use of FHIR and on addressing the White House Executive Order related to health equity in the HQRP.

Finally, in section III.G of this rule, we are finalizing our proposal to the HH QRP so that, beginning with the January 2022 through the July 2024 public reporting refresh cycle, we will report fewer quarters of data due to COVID–19 PHE exceptions granted on March 27, 2020. We included the HH QRP policy in this rulemaking in order to resume public reporting for the HH QRP with the January 2022 refresh of Care Compare. To accommodate the excepted HH QRP of 2020 Q1 and Q2, we resume public reporting using 3 out of 4 quarters of data for the January 2022 refresh. In order to finalize this proposal in time to release the required preview report related to the January 2022 refresh, which we release 3 months prior to any given refresh (October

2021), we needed the rule containing this proposal to finalize by October 2021.

C. Summary of Impacts

The overall economic impact of this final rule is estimated to be $480 million in increased payments to hospices for FY 2022.

II. Background

A. Hospice Care

Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. Medicare regulations define ''palliative care'' as patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice (42 CFR 418.3). Palliative care is at the core of hospice philosophy and care practices, and is a critical component of the Medicare hospice benefit.

The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. Hospice is compassionate beneficiary and family/caregiver-centered care for those who are terminally ill.

As referenced in our regulations at § 418.22(b)(1), to be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual is ''terminally ill,'' as defined in section 1861(dd)(3)(A) of the Social Security Act (the Act) and our regulations at § 418.3; that is, the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course. The regulations at § 418.22(b)(2) require that clinical information and other documentation that support the medical prognosis accompany the certification and be filed in the medical record with it and those at § 418.22(b)(3) require that the certification and recertification forms include a brief narrative explanation of the clinical findings that support a life expectancy of 6 months or less.

Under the Medicare hospice benefit, the election of hospice care is a patient choice and once a terminally ill patient elects to receive hospice care, a hospice interdisciplinary group is essential in the seamless provision of primarily home-based services. The hospice interdisciplinary group works with the beneficiary, family, and caregivers to develop a coordinated, comprehensive care plan; reduce unnecessary diagnostics or ineffective therapies; and maintain ongoing communication with individuals and their families about changes in their condition. The beneficiary's care plan will shift over time to meet the changing needs of the individual, family, and caregiver(s) as the individual approaches the end of life.

If, in the judgment of the hospice interdisciplinary team, which includes the hospice physician, the patient's symptoms cannot be effectively managed at home, then the patient is eligible for general inpatient care (GIP), a more medically intense level of care. GIP must be provided in a Medicare-certified hospice freestanding facility, skilled nursing facility, or hospital. GIP is provided to ensure that any new or worsening symptoms are intensively addressed so that the beneficiary can return to his or her home and continue to receive routine home care. Limited, short-term, intermittent, inpatient respite care (IRC) is also available because of the absence or need for relief of the family or other caregivers. Additionally, an individual can receive continuous home care (CHC) during a period of crisis in which an individual requires continuous care to achieve palliation or management of acute medical symptoms so that the individual can remain at home. Continuous home care may be covered for as much as 24 hours a day, and these periods must be predominantly nursing care, in accordance with the regulations at § 418.204. A minimum of 8 hours of nursing care, or nursing and aide care, must be furnished on a particular day to qualify for the continuous home care rate (§ 418.302(e)(4)).

Hospices must comply with applicable civil rights laws,[1] including section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, under which covered entities must take appropriate steps to ensure effective communication with patients and patient care representatives with disabilities, including the provisions of auxiliary aids and services at no cost to the individual. Additionally, they must take reasonable steps to ensure meaningful access for individuals with limited English proficiency, consistent with Title VI of the Civil Rights Act of 1964. Further information about these requirements may be found at: *http://www.hhs.gov/ocr/civilrights.*

B. Services Covered by the Medicare Hospice Benefit

Coverage under the Medicare hospice benefit requires that hospice services must be reasonable and necessary for the palliation and management of the terminal illness and related conditions. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare-certified hospice program. These covered services include: Nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologicals); medical appliances; counseling services (including dietary counseling); short-term inpatient care in a hospital, nursing facility, or hospice inpatient facility (including both respite care and procedures necessary for pain control and acute or chronic symptom management); continuous home care during periods of crisis, and only as necessary to maintain the terminally ill individual at home; and any other item or service which is specified in the plan of care and for which payment may otherwise be made under Medicare, in accordance with Title XVIII of the Act.

Section 1814(a)(7)(B) of the Act requires that a written plan for providing hospice care to a beneficiary who is a hospice patient be established before care is provided by, or under arrangements made by, the hospice program; and that the written plan be periodically reviewed by the beneficiary's attending physician (if any), the hospice medical director, and an interdisciplinary group (section 1861(dd)(2)(B) of the Act). The services offered under the Medicare hospice benefit must be available to beneficiaries as needed, 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act).

Upon the implementation of the hospice benefit, the Congress also expected hospices to continue to use volunteer services, though Medicare

[1] Hospices are also subject to additional Federal civil rights laws, including the Age Discrimination Act, Section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

does not pay for these volunteer services (section 1861(dd)(2)(E) of the Act). As stated in the Fiscal Year (FY) 1983 Hospice Wage Index and Rate Update proposed rule (48 FR 38149), the hospice must have an interdisciplinary group composed of paid hospice employees as well as hospice volunteers, and that ''the hospice benefit and the resulting Medicare reimbursement is not intended to diminish the voluntary spirit of hospices.'' This expectation supports the hospice philosophy of community based, holistic, comprehensive, and compassionate end of life care.

C. Medicare Payment for Hospice Care

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and the regulations in 42 CFR part 418, establish eligibility requirements, payment standards and procedures; define covered services; and delineate the conditions a hospice must meet to be approved for participation in the Medicare program. Part 418, subpart G, provides for a per diem payment based on one of four prospectively-determined rate categories of hospice care (routine home care (RHC), CHC, IRC, and GIP), based on each day a qualified Medicare beneficiary is under hospice care (once the individual has elected). This per diem payment is meant to cover all of the hospice services and items needed to manage the beneficiary's care, as required by section 1861(dd)(1) of the Act.

While payments made to hospices are to cover all items, services, and drugs for the palliation and management of the terminal illness and related conditions, Federal funds cannot be used for the prohibited activities, even in the context of a per diem payment. While recent news reports [2] have brought to light the potential role hospices could play in medical aid in dying (MAID) where such practices have been legalized in certain states, we wish to remind hospices that The Assisted Suicide Funding Restriction Act of 1997 (Pub. L. 105–12) prohibits the use of Federal funds to provide or pay for any health care item or service or health benefit coverage for the purpose of causing, or assisting to cause, the death of any individual including mercy killing, euthanasia, or assisted suicide. However, the prohibition does not pertain to the provision of an item or service for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as the item or service is not furnished for the specific purpose of causing or accelerating death.

1. Omnibus Budget Reconciliation Act of 1989

Section 6005(a) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) amended section 1814(i)(1)(C) of the Act and provided changes in the methodology concerning updating the daily payment rates based on the hospital market basket percentage increase applied to the payment rates in effect during the previous Federal fiscal year.

2. Balanced Budget Act of 1997

Section 4441(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established that updates to the hospice payment rates beginning FY 2002 and subsequent FYs be the hospital market basket percentage increase for the FY. Section 4442 of the BBA amended section 1814(i)(2) of the Act, effective for services furnished on or after October 1, 1997, to require that hospices submit claims for payment for hospice care furnished in an individual's home only on the basis of the geographic location at which the service is furnished. Previously, local wage index values were applied based on the geographic location of the hospice provider, regardless of where the hospice care was furnished. Section 4443 of the BBA amended sections 1812(a)(4) and 1812(d)(1) of the Act to provide for hospice benefit periods of two 90-day periods, followed by an unlimited number of 60-day periods.

3. FY 1998 Hospice Wage Index Final Rule

The FY 1998 Hospice Wage Index final rule (62 FR 42860), implemented a new methodology for calculating the hospice wage index and instituted an annual Budget Neutrality Adjustment Factor (BNAF) so aggregate Medicare payments to hospices would remain budget neutral to payments calculated using the 1983 wage index.

4. FY 2010 Hospice Wage Index Final Rule

The FY 2010 Hospice Wage Index and Rate Update final rule (74 FR 39384) instituted an incremental 7-year phase-out of the BNAF beginning in FY 2010 through FY 2016. The BNAF phase-out reduced the amount of the BNAF increase applied to the hospice wage index value, but was not a reduction in the hospice wage index value itself or in the hospice payment rates.

5. The Affordable Care Act

Starting with FY 2013 (and in subsequent FYs), the market basket percentage update under the hospice payment system referenced in sections 1814(i)(1)(C)(ii)(VII) and 1814(i)(1)(C)(iii) of the Act are subject to annual reductions related to changes in economy-wide productivity, as specified in section 1814(i)(1)(C)(iv) of the Act.

In addition, sections 1814(i)(5)(A) through (C) of the Act, as added by section 3132(a) of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148), required hospices to begin submitting quality data, based on measures specified by the Secretary of the Department of Health and Human Services (the Secretary), for FY 2014 and subsequent FYs. Since FY 2014, hospices that fail to report quality data have their market basket percentage increase reduced by 2 percentage points. Note that with the passage of the Consolidated Appropriations Act, 2021 (hereafter referred to as CAA 2021) (Pub. L. 116 260), the reduction changes to 4 percentage points beginning in FY 2024.

Section 1814(a)(7)(D)(i) of the Act, as added by section 3132(b)(2) of the PPACA, required, effective January 1, 2011, that a hospice physician or nurse practitioner have a face-to-face encounter with the beneficiary to determine continued eligibility of the beneficiary's hospice care prior to the 180th day recertification and each subsequent recertification, and to attest that such visit took place. When implementing this provision, the Centers for Medicare & Medicaid Services (CMS) finalized in the FY 2011 Hospice Wage Index final rule (75 FR 70435) that the 180th day recertification and subsequent recertifications would correspond to the beneficiary's third or subsequent benefit periods. Further, section 1814(i)(6) of the Act, as added by section 3132(a)(1)(B) of the PPACA, authorized the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and other purposes. The types of data and information suggested in the PPACA could capture accurate resource utilization, which could be collected on claims, cost reports, and possibly other mechanisms, as the Secretary determined to be appropriate. The data collected could be used to revise the methodology for determining the payment rates for RHC and other services included in hospice care, no earlier than October 1, 2013, as described in section 1814(i)(6)(D) of the Act. In addition, CMS was required to

[2] Nelson, R., Should Medical Aid in Dying Be Part of Hospice Care? Medscape Nurses. February 26, 2020. *https://www.medscape.com/viewarticle/925769#vp_1.*

consult with hospice programs and the Medicare Payment Advisory Commission (MedPAC) regarding additional data collection and payment revision options.

6. FY 2012 Hospice Wage Index Final Rule

In the FY 2012 Hospice Wage Index final rule (76 FR 47308 through 47314) it was announced that beginning in 2012, the hospice aggregate cap would be calculated using the patient-by-patient proportional methodology, within certain limits. Existing hospices had the option of having their cap calculated through the original streamlined methodology, also within certain limits. As of FY 2012, new hospices have their cap determinations calculated using the patient-by-patient proportional methodology.

7. IMPACT Act of 2014

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185) became law on October 6, 2014. Section 3(a) of the IMPACT Act mandated that all Medicare certified hospices be surveyed every 3 years beginning April 6, 2015 and ending September 30, 2025. In addition, section 3(c) of the IMPACT Act requires medical review of hospice cases involving beneficiaries receiving more than 180 days of care in select hospices that show a preponderance of such patients; section 3(d) of the IMPACT Act contains a new provision mandating that the cap amount for accounting years that end after September 30, 2016, and before October 1, 2025 be updated by the hospice payment percentage update rather than using the consumer price index for urban consumers (CPI–U) for medical care expenditures.

8. FY 2015 Hospice Wage Index and Payment Rate Update Final Rule

The FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50452) finalized a requirement that the Notice of Election (NOE) be filed within 5 calendar days after the effective date of hospice election. If the NOE is filed beyond this 5-day period, hospice providers are liable for the services furnished during the days from the effective date of hospice election to the date of NOE filing (79 FR 50474). As with the NOE, the claims processing system must be notified of a beneficiary's discharge from hospice or hospice benefit revocation within 5 calendar days after the effective date of the discharge/revocation (unless the hospice has already filed a final claim) through the submission of a final claim or a Notice of Termination or Revocation (NOTR).

The FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50479) also finalized a requirement that the election form include the beneficiary's choice of attending physician and that the beneficiary provide the hospice with a signed document when he or she chooses to change attending physicians.

In addition, the FY 2015 Hospice Wage Index and Rate Update final rule (79 FR 50496) provided background, described eligibility criteria, identified survey respondents, and otherwise implemented the Hospice Experience of Care Survey for informal caregivers. Hospice providers were required to begin using this survey for hospice patients as of 2015.

Finally, the FY 2015 Hospice Wage Index and Rate Update final rule required providers to complete their aggregate cap determination not sooner than 3 months after the end of the cap year, and not later than 5 months after, and remit any overpayments. Those hospices that fail to submit their aggregate cap determinations on a timely basis will have their payments suspended until the determination is completed and received by the Medicare contractor (79 FR 50503).

9. FY 2016 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47142), CMS finalized two different payment rates for RHC: A higher per diem base payment rate for the first 60 days of hospice care and a reduced per diem base payment rate for subsequent days of hospice care. CMS also finalized a service intensity add-on (SIA) payment payable for certain services during the last 7 days of the beneficiary's life. A service intensity add-on payment will be made for the social worker visits and nursing visits provided by a registered nurse (RN), when provided during routine home care in the last 7 days of life. The SIA payment is in addition to the routine home care rate. The SIA payment is provided for visits of a minimum of 15 minutes and a maximum of 4 hours per day (80 FR 47172).

In addition to the hospice payment reform changes discussed, the FY 2016 Hospice Wage Index and Rate Update final rule implemented changes mandated by the IMPACT Act, in which the cap amount for accounting years that end after September 30, 2016 and before October 1, 2025 would be updated by the hospice payment update percentage rather than using the CPI–U (80 FR 47186). In addition, we finalized a provision to align the cap accounting year for both the inpatient cap and the hospice aggregate cap with the FY for FY 2017 and thereafter. Finally, the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47144) clarified that hospices would have to report all diagnoses on the hospice claim as a part of the ongoing data collection efforts for possible future hospice payment refinements.

10. FY 2017 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2017 Hospice Wage Index and Rate Update final rule (81 FR 52160), CMS finalized several new policies and requirements related to the Hospice Quality Reporting Program (HQRP). First, CMS codified the policy that if the National Quality Forum (NQF) made non-substantive changes to specifications for HQRP measures as part of the NQF's re-endorsement process, CMS would continue to utilize the measure in its new endorsed status, without going through new notice-and-comment rulemaking. CMS would continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures adopted for the HQRP; determinations about what constitutes a substantive versus non-substantive change would be made on a measure-by-measure basis. Second, we finalized two new quality measures for the HQRP for the FY 2019 payment determination and subsequent years: Hospice Visits when Death is Imminent Measure Pair and Hospice and Palliative Care Composite Process Measure-Comprehensive Assessment at Admission (81 FR 52173). The data collection mechanism for both of these measures is the Hospice Item Set (HIS), and the measures were effective April 1, 2017. Regarding the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey, CMS finalized a policy that hospices that receive their CMS Certification Number (CCN) after January 1, 2017 for the FY 2019 Annual Payment Update (APU) and January 1, 2018 for the FY 2020 APU will be exempted from the Hospice CAHPS® requirements due to newness (81 FR 52182). The exemption is determined by CMS and is for 1 year only.

11. FY 2020 Hospice Wage Index and Payment Rate Update Final Rule

In the FY 2020 Hospice Wage Index and Rate Update final rule (84 FR 38484), we finalized rebased payment rates for CHC and GIP and set those rates equal to their average estimated FY 2019 costs per day. We also rebased IRC per diem rates equal to the estimated FY

2019 average costs per day, with a reduction of 5 percent to the FY 2019 average cost per day to account for coinsurance. We finalized the FY 2020 proposal to reduce the RHC payment rates by 2.72 percent to offset the increases to CHC, IRC, and GIP payment rates to implement this policy in a budget-neutral manner in accordance with section 1814(i)(6) of the Act (84 FR 38496).

In addition, we finalized a policy to use the current year's pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the hospice rates. Finally, in the FY 2020 Hospice Wage Index and Rate Update final rule (84 FR 38505), we finalized modifications to the hospice election statement content requirements at § 418.24(b) by requiring hospices, upon request, to furnish an election statement addendum effective beginning in FY 2021. The addendum must list those items, services, and drugs the hospice has determined to be unrelated to the terminal illness and related conditions, increasing coverage transparency for beneficiaries under a hospice election.

12. Consolidated Appropriations Act, 2021

Division CC, section 404 of Consolidated Appropriations Act, 2021 (CAA 2021) amended section 1814(i)(2)(B) of the Act and extended the provision that currently mandates the hospice cap be updated by the hospice payment update percentage (hospital market basket update reduced by the productivity adjustment) rather than the CPI–U for accounting years that end after September 30, 2016 and before October 1, 2030. Prior to enactment of this provision, the hospice cap update was set to revert to the original methodology of updating the annual cap amount by the CPI–U beginning on October 1, 2025. Division CC, section 407 of CAA 2021 revises section 1814(i)(5)(A)(i) to increase the payment reduction for hospices who fail to meet hospice quality measure reporting requirements from two percent to four percent beginning with FY 2024.

III. Provisions of the Final Rule

A. Hospice Utilization and Spending Patterns

In the FY 2022 proposed rule (86 FR 19700), CMS provided data analysis on hospice utilization trends from FY 2010 through FY 2019. The analysis included data on the number of beneficiaries using the hospice benefit, live discharges, reported diagnoses on hospice claims, Medicare hospice spending, and Parts A, B and D non-hospice spending during a hospice election. The proposed rule also solicited comments from the public, hospice providers, patients and advocates regarding hospice utilization and spending patterns. We also solicited comments regarding skilled visits in the last week of life, particularly, what factors determine how and when visits are made as an individual approaches the end of life and how hospices make determinations as to what items, services and drugs are related versus unrelated to the terminal illness and related conditions. That is, how do hospices define what is unrelated to the terminal illness and related conditions when establishing a hospice plan of care.

Likewise, we solicited comments on what other factors may influence whether or how certain services are furnished to hospice beneficiaries. Finally, we requested feedback from stakeholder as to whether the hospice election statement addendum has changed the way hospices make care decisions and how the addendum is used to prompt discussions with beneficiaries and non-hospice providers to ensure that the care needs of beneficiaries who have elected the hospice benefit are met. A summary of these comments and our response to those comments appear below:

1. Hospice Utilization and Spending Patterns

Several commenters thanked CMS for continuing to incorporate monitoring and data analysis into its proposed hospice payment rule. Many commenters stated that while the structure of the hospice benefit and approach to care at the end of life remain unchanged, changes in the characteristics of patients served (particularly the shift from predominantly cancer patients to those with end-stage neurological and other conditions) is largely responsible for driving changes in utilization trends and hospice practice over recent decades. Many commenters suggested that CMS provide more detailed analysis of physician billing as it relates to non-hospice spending and a few commenters suggested that CMS release additional data connected to CMS' Part D spending analysis to better inform stakeholders and assist in helping to determine what factors may be contributing to these increased Part D expenditures during a hospice election.

2. Skilled Visits in the Last Days of Life

One commenter stated that the service intensity add-on (SIA) payment has been one of the greatest improvements in the hospice benefit in recent years. Many commenters recommended that CMS modify the SIA payments to include any visits which could be counted toward end-of-life care, not just skilled visits (for example, chaplain and spiritual care or hospice aide).

3. Items, Services, and Drugs Related and Unrelated to the Terminal Illness and Related Conditions

Several commenters stated that the determination of relatedness, as applied to coverage decisions connected to terminal prognosis, is a clinical decision specific to the unique clinical circumstances of each patient. Several commenters stated that they work in collaboration with their respective IDGs to determine the items, services, and drugs that are related versus unrelated once the comprehensive assessment is completed.

4. Election Statement Addendum

Several commenters stated that the addendum has not changed their practices for determining what is related or unrelated under the hospice benefit, but has enhanced the upfront communication with patients and representatives during the admission process. One commenter stated that their hospice revisited the way relatedness is defined, and realized that many diagnoses that were previously thought to be unrelated were related. Another commenter stated that very few patients and their representatives have requested the addendum and that the burden of implementation of the addendum outweighs the benefits.

We appreciate the comments provided regarding the analysis presented in the proposed rule. We plan continue to monitor hospice trends and vulnerabilities within the hospice benefit. We will consider these comments and suggestions for ongoing monitoring analyses, program integrity efforts, and for potential future rulemaking.

B. FY 2022 Labor Shares

1. Background

The labor share for CHC and RHC of 68.71 percent was established with the FY 1984 Hospice benefit implementation based on the wage/nonwage proportions specified in Medicare's limit on home health agency costs (48 FR 38155 through 38156). The labor shares for IRC and GIP are currently 54.13 percent and 64.01 percent, respectively. These proportions were based on skilled nursing facility wage and nonwage cost limits and

skilled nursing facility costs per day (48 FR 38155 through 38156; 56 FR 26917).

In the FY 2022 proposed rule (86 FR 19717 through 19719), we proposed to rebase and revise the labor shares for CHC, RHC, IRC and GIP using Medicare cost report (MCR) data for freestanding hospices (collected via CMS Form 1984–14, OMB NO. 0938–0758) for 2018. We proposed to continue to establish separate labor shares for CHC, RHC, IRC, and GIP and base them on the calculated compensation cost weights for each level of care from the 2018 MCR data. We describe our proposed methodology for deriving the compensation cost weights for each level of care using the MCR data below as well as a summary of the comments received and our responses.

Twenty unique stakeholders submitted their comments on the proposal to rebase the hospice labor shares. In response to public comments, we are adopting the revised hospice labor shares calculated as we proposed with a slight modification to the methodology.

Comment: A few commenters supported the proposal to rebase the labor share for the four levels of care based on the 2018 MCR data. One commenter supported the proposed methodology of using actual hospice cost report data calculated using all applicable costs as well as including only providers who performed each level of care normalizing for outliers. Another commenter stated it was appropriate that the hospice labor shares be based on data for hospice providers, rather than home health agencies and skilled nursing facilities. Several commenters stated that basing the hospice labor shares on recent MCR data for hospice providers will improve payment accuracy.

One commenter strongly encouraged CMS not to revise the labor share using the 2018 MCR for freestanding hospices. One commenter opposed the proposed labor shares, stating that the data in the cost report do not provide adequate or appropriate measures of labor expenses. One commenter agreed with the increased labor share for CHC and for IRC, but did not agree with lowering the labor share for RHC and GIP. One commenter acknowledged the rationale for using hospice cost report data, but stated that this will reduce reimbursement for many of their members, particularly those who provide more GIP than average.

Response: We believe that our proposal to revise the labor shares based on MCR data for hospice providers is a technical improvement to the current labor shares and appreciate the support from the commenters.

We disagree with commenters that the hospice MCR data does not provide adequate or appropriate measure of labor expenses. The MCR data captures detailed labor and non-labor expenses for patient (including but not limited to nursing, physician, therapy and medical supply expenses) and non-patient expenses (such as administrative and general) by level of care. We would note that the freestanding hospice MCR data was used to rebase the hospice payment rates effective for FY 2020 (84 FR 38487 to 38496). In addition, we remind providers that when submitting the MCR data they must certify the cost report that ''to the best of [their] knowledge and belief, [the] report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted.''

Comment: Several commenters expressed concern regarding the impact of COVID–19 on labor costs. Commenters stated that while they do not yet know the full extent of the impact on labor costs, they expect it to be significant. They stated that the PHE could considerably change the labor share in the next several years of cost report data, as the use of cost reports has a 2-year delay in data. These commenters stated that the impact of COVID–19 on the labor component of the rates cannot be captured in cost report data that is at least 2 years old. The commenters requested consideration of the impact of COVID–19 when setting labor shares for future years.

Several other commenters stated that hospices face significant challenges in the labor market, particularly for nurses. They stated that more nurses are retiring, competition for available nurses is fierce, and many hospices are paying premium salaries and bonuses to recruit and retain qualified nursing staff. One commenter stated that the hospice per diem structure severely limits the amounts they can spend on staff. One commenter stated during the pandemic more time has been needed to train and retrain on infection control standards, as well as changes in communication due to practice changes.

One commenter stated that it is difficult to attract nurses to their geographic area because of the increase in the median home price between January 2021 and May 2021. The commenter stated that they are forced to outsource many nursing functions at high cost, along with paying retention bonuses to current staff. The commenter stated that these labor market challenges will have an impact on the labor shares, which will not necessarily be reflected when the cost report data used is 2 years old. One commenter urged CMS to give special consideration to challenges faced by rural health care providers with specific attention given to the impact workforce shortages have in setting reimbursement rates related to the labor shares.

Response: We acknowledge and appreciate the commenters' concerns regarding labor costs and understand the challenges created by the PHE. We believe using updated labor shares based on 2018 data is a technical improvement over the current labor shares as they reflect recent cost data for freestanding hospice providers. The current labor shares were primarily based on data from the early 1980s. The proposed labor shares reflect the skilled care (including the number of visits) provided under the hospice per diem payment rates for each level of care. For example, the higher labor share for CHC compared to RHC reflects the higher number of visits per day provided with CHC relative to RHC. The current labor shares did not reflect this differential in utilization as the same labor share was used for both levels of care.

We plan on reviewing the 2020 hospice MCR data when complete information is available that will allow us to consider whether the hospice labor shares based on 2018 data are still appropriate. Any future revisions to the hospice labor shares will be proposed and subject to public comments in future rulemaking.

Comment: Several commenters expressed concerns about the frequency of updating the labor shares in the future. A few of these commenters requested that CMS provide further clarification of the frequency of updates to the labor shares with hospice cost report data. One commenter stated that it is important that CMS address this frequency so that hospices and cost report preparers can ensure that the data submitted on the cost report can be used for the labor share calculations.

Response: We acknowledge the commenters' concern that the proposed rule did not explicitly state when we plan to propose any revisions to the hospice labor shares beyond FY 2022.

The labor shares for other PPS systems (for example, IPPS, SNF, IRF, IPF, and LTCH) are typically rebased every four to five years. We tentatively plan to rebase the hospice labor shares on a similar schedule as the other payment systems under Medicare. However, in light of the COVID–19 PHE, we plan to monitor the upcoming MCR

data to see if a more frequent revision to the hospice labor shares is necessary in order to reflect the most recent cost structures of hospice providers. We note that any future revisions to the hospice labor shares will be proposed and subject to public comments in future rulemaking.

Comment: A few commenters stated that while they understand the desire and rationale for using hospice data to revise the hospice labor shares (and to make other policy changes), they believe it is important to recognize that the data inputs utilized must be appropriate to the task. The commenters stated that the hospice cost report in its current form does not suit all data purposes for hospice policy changes, and does not fully support calculation of the hospice payment rate labor shares.

One commenter noted that the hospice cost report for freestanding providers is being proposed to be used for the first time to determine the labor component of the rates for each level of care. While the commenter commended CMS for using hospice-specific data, they were also concerned about the accuracy of the data submitted by providers.

One commenter stated concern that due to hospice MCRs not being audited, as well as some sections of the cost report offering multiple methods of reporting, there is a general lack of consistency in the way that the reports are completed by hospice providers that will necessarily distort the average labor figures. The commenter was also concerned that it's not likely that most payroll applications used by hospice providers can correctly allocate costs by level of care, so due to different methods applied by hospice providers to estimate this, the labor costs will also be impacted.

One commenter stated that there are no checks and balances on whether cost reporting data are accurate. They claimed that classifying costs across the four levels of care can contain inaccuracies, particularly when staff allocate time to various levels of care in the same working day. The commenter stated that there are no regulations that require cost reports to be completed by an outside or otherwise qualified accounting firm, and many hospices are doing their own costs reports without complete understanding of how to allocate specific costs and which box is appropriate for particular costs. They stated that the number of hospices that do not pass level 1 edits is also of concern.

One commenter stated that they do not believe hospice cost reports are historically very accurate. They stated that in many healthcare systems someone from the accounting department completed the cost report form with very little input from the hospice program. The commenter stated that they never had an opportunity to review the cost report prior to submission to verify the information was accurate and that they believe this is a common occurrence across the country. Therefore, the commenter stated that they do not believe that cost reports capture labor costs very accurately.

A few commenters stated that if data from the hospice cost report is to be used for calculating the labor component by level of care, revisions to the cost report should be proposed to address current inconsistent, but acceptable, reporting practices. Further, the commenters stated that these changes should be instituted to ensure greater accuracy of the data being used to establish labor shares for GIP and IRC. A few commenters stated that these changes should be implemented as quickly as possible, and once they are in place CMS should undertake a recalculation of the labor shares.

Response: The freestanding hospice MCR form used for the proposed labor shares (CMS–1984–14; OMB NO. 0938–0758) was revised effective for cost reporting periods beginning on or after October 1, 2014 in response to section 1814(i)(6) of the Act, as added by section 3132(a)(1)(B) of the PPACA, which authorized the Secretary to collect additional data and information determined appropriate to revise payments for hospice care and other purposes. The types of data and information suggested in the PPACA could capture accurate resource utilization, which could be collected on claims, cost reports, and possibly other mechanisms, as the Secretary determined to be appropriate.

CMS form 1984–14 was proposed and subject to public comments. Hospice providers previously completed MCR form (CMS–1984–89, OMB NO. 0938–0758). The revised MCR enabled CMS to collect more detailed data regarding labor costs by level of care. The prior MCR did not collect total costs by level of care or detailed costs by level of care (such as labor and nonlabor).

We disagree with the commenter that the cost report in its current form does not support the calculation of the hospice payment rate labor shares. Providers are required to report detailed patient costs (including but not limited to nursing, physician, therapy, and medical supplies) and non-patient costs for each level of care. These costs are further subdivided into labor and non-labor costs.

Our proposal to use the 2018 MCR data recognizes that providers have had 4 years to familiarize themselves with the form and, thereby, improve the accuracy of the data. We note that based on comments received during the CMS–1984–14; OMB NO. 0938–0758 clearance process, the implementation of the MCR form was delayed to October 1, 2014. In addition, as stated previously, providers must certify the cost report that ''to the best of [their] knowledge and believe, [the] report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted.'' Nonetheless, we recognize that data can be misreported at times and, therefore, our proposal for revising the labor shares included applying several edits to remove possible outlier data—a common statistical practice.

We continue to encourage hospice providers to report accurate and complete data on the cost reports. We will evaluate and consider any future changes to the hospice cost report that will allow for the collection of data that may improve the calculation of the hospice labor shares. In addition, we will monitor the compensation cost weights reported by hospices over time to determine if changes to the labor share are appropriate. Any future changes to the cost report or labor shares would be subject to public comments.

While we acknowledge that hospice providers can use different methodologies for reporting data, we believe that our proposed methodology allows for these differences and still results in a reasonable and accurate measure of the cost structures of hospice facilities.

The proposed labor shares are based on MCR data for freestanding hospice facilities. As stated in the proposed rule, we did explore the possibility of using facility-based hospice MCR data to calculate the compensation cost weights; however, very few providers passed the Level I edits (as described in more detail below) and so these reports were not usable.

Comment: One commenter stated that the finances of freestanding hospices are significantly different than those of hospices based at hospitals, home health agencies and nursing homes; therefore, data from freestanding hospices should not be allowed to represent the industry as a whole.

Response: As stated in the FY 2022 Hospice Wage Index and Rate Update proposed rule (86 FR 19717), we did

explore the possibility of using facility-based hospice MCR data to calculate the compensation cost weights; however, very few providers passed the Level I edits and so these reports were not usable. We also plan to continue to review the 2020 hospital-based hospice MCR data to see if the reporting of the detailed expense data by level of care has improved for possible incorporation into the labor share calculations. We would note that the freestanding hospice providers account for about 85 percent of hospice providers and therefore, we believe our proposal to use only the freestanding hospice MCR data to revise the labor shares is reasonable and a technical improvement over the current labor shares.

2. Methodology for Calculating Compensation Costs

We proposed to derive a compensation cost weight for each level of care that consists of five major components: (1) Direct patient care salaries and contract labor costs, (2) direct patient care benefits costs, (3) other patient care salaries, (4) overhead salaries, and (5) overhead benefits costs. For each level of care, we proposed to use the same methodology to derive the components; however, for the (1) direct patient care salaries and (3) other patient care salaries, we proposed to use the MCR worksheet that is specific to that level of care (that is, Worksheet A–1 for CHC, Worksheet A–2 for RHC, Worksheet A–3 for IRC, and Worksheet A–4 for GIP).

a. Direct Patient Care Salaries and Contract Labor Costs

Direct patient care salaries and contract labor costs are costs associated with medical services provided by medical personnel including but not limited to physician services, nurse practitioners, RNs, and hospice aides. We proposed to define direct patient care salaries and contract labor costs to be equal to costs reported on Worksheet A–1 (for CHC) or Worksheet A–2 (for RHC) or Worksheet A–3 (for IRC) or Worksheet A–4 (for GIP), column 7, for lines 26 through 37.

Comment: One specific concern of the commenters regarding the proposed methodology was on the data used from Worksheet A–1 and A–2 column 7, lines 26 through 37 for total labor costs associated with each respective level of care. The commenters stated that certain costs are not consistently reported by hospices despite these costs being in compliance with cost reporting instructions. For example, the commenters provided that some hospices track mileage allowances enabling them to be reported on Worksheet A–1 and A–2 while other hospices allocate these mileage reimbursement costs via Worksheet B and B–1 using miles traveled. The commenters asked CMS whether any consideration was given to this inconsistent, but acceptable, reporting for mileage allowances.

Response: We appreciate the commenter's concern. The proposed methodology for calculating the labor shares cited by the commenter of using Worksheet A–1 and A–2 column 7, lines 26 through 37 for total labor costs reflects only one component of the proposed calculation of the labor share. As discussed in the FY 2022 Hospice proposed rule (86 FR 19718) and above, we proposed to derive Direct patient care salaries and contract labor costs using (for CHC as an example) Worksheet A–1 column 7, lines 26 through 37 on the cost report, which would capture any staff transportation costs reported in these cost centers on Worksheet A–1.

Also included in the compensation costs for each level of care, as discussed in the FY 2022 Hospice proposed rule (86 FR 19718) and below, is a proportion overhead salaries and benefits. The overhead salaries includes those reported in the staff transportation cost center (reported in Worksheet A, column 1, line 12) and the overhead benefits for the staff transportation cost center (Worksheet B, column 3, line 12).

Therefore, after consideration of public comments, we believe that our proposed methodology is capturing both the direct patient care costs reported on Worksheet A–1 and any overhead salaries and overhead benefits related to staff transportation costs that are allocated on Worksheet B. We believe that the non-salary non-benefit costs for staff transportation that are allocated on Worksheet B (for example, cost of owning or renting vehicles) should not be included in the labor share of the hospice payment rate that is adjusted by the wage index, as they are not compensation costs, nor do they vary with the local labor market.

b. Direct Patient Care Benefits Costs

We proposed that direct patient care benefits costs for CHC are equal to Worksheet B, column 3, line 50, for RHC are equal to Worksheet B, column 3, line 51, for IRC are equal to Worksheet B, column 3, line 52, and for GIP are equal to Worksheet B, column 3, line 53.

c. Other Patient Care Salaries

Other patient care salaries are those salaries attributable to patient services including but not limited to patient transportation, labs, and imaging services. These salaries reflecting all levels of care are reported on Worksheet A, column 1, lines 38 through 46 and then are further disaggregated for CHC, RHC, IRC, and GIP on Worksheets A–1, A–2, A–3, and A–4, respectively, on column 1 (salaries), lines 38 through 46. Our analysis, however, found that many providers were not reporting salaries on the detailed level of care worksheets (A–1, A–2, A–3, A–4, column 1), but rather reporting total costs (reflecting salary and nonsalary costs) for these services for each level of care on Worksheets A–1, A–2, A–3, A–4, column 7. Therefore, we proposed to estimate other patient care salaries attributable to CHC, RHC, IRC, and GIP by first calculating the ratio of total facility (reflecting all levels of care) other patient care salaries (Worksheet A, column 1, lines 38 through 46) to total facility other patient care total costs (Worksheet A, column 7, lines 38 through 46). For CHC, we proposed to then multiply this ratio by other patient care total costs for CHC (Worksheet A–1 column 7, lines 38 through 46). For RHC, we proposed to multiply this ratio by total other patient care costs for RHC (Worksheet A–2, column 7, lines 38 through 46). For IRC, we proposed to multiply this ratio by total other patient care costs for IRC (Worksheet A–3, column 7, lines 38 through 46). For GIP, we proposed to multiply this ratio by total other patient care costs for GIP (Worksheet A–4, column 7, lines 38 through 46). This proposed methodology assumes that the proportion of salary costs to total costs for other patient care services is consistent for each of the four levels of care.

Comment: One commenter stated that the proposed methodology for calculating compensation costs omits two of the required disciplines in a hospice patient's interdisciplinary team. They stated that social workers and counselors provide direct patient care along with nurses and hospice aides in both routine home care and general inpatient care. The commenter claimed that the proposed methodology only captures salaries and benefits of physicians, nurse practitioners, RNs and hospice aides. The commenter stated that this disregards the essence of the hospice interdisciplinary team which cares for the patient and family as a unit of care. Social workers and counselors serve both the patient and their family. Their salaries and benefits must also be captured in the methodology. The commenter stated that it is unclear in the proposed rule whether they are

included in ''Other Patient Care Salaries'' since only mentioned are patient transportation, labs and imaging services.

Response: As stated in the FY 2022 hospice proposed rule (86 FR 19717 through 19719) as well as above, we proposed that Direct patient care salaries and contract labor costs be equal to costs reported on Worksheet A–1 (for CHC) or Worksheet A–2 (for RHC) or Worksheet A–3 (for IRC) or Worksheet A–4 (for GIP), column 7, for lines 26 through 37 (86 FR 19718). These lines include Medical Social Services (line 33), Spiritual Counseling (line 34), Dietary Counseling (line 25), and Counseling Other (line 36). Therefore, we proposed to include direct patient care salaries and contract labor for social workers and counselors in the calculation of the labor shares.

d. Overhead Salaries

The MCR captures total overhead costs (including but not limited to administrative and general, plant operations and maintenance, and housekeeping) attributable to each of the four levels of care. To estimate overhead salaries for each level of care, we first proposed to calculate noncapital nonbenefit overhead costs for each level of care to be equal to Worksheet B, column 18, less the sum of Worksheet B, columns 0 through 3, for line 50 (CHC), or line 51 (RHC) or line 52 (IRC) or line 53 (GIP). We then proposed to multiply these noncapital nonbenefit overhead costs for each level of care times the ratio of total facility overhead salaries (Worksheet A, column 1, lines 4 through 16) to total facility noncapital nonbenefit overhead costs (which is equal to Worksheet B, column 18 (total costs), line 101 less the sum of Worksheet B, columns 0 (direct patient care costs), column 1 (fixed capital), column 2 (moveable capital) and column 3 (employee benefits), line 101).

e. Overhead Benefits Costs

To estimate overhead benefits costs for each level of care, we proposed a similar methodology to overhead salaries. For each level of care, we proposed to calculate noncapital overhead costs for each level of care to be equal to Worksheet B, column 18, less the sum of Worksheet B, columns 0 through 2, for line 50 (CHC), or line 51 (RHC) or line 52 (IRC) or line 53 (GIP). We then proposed to multiply these noncapital overhead costs for each level of care times the ratio of total facility overhead benefits (Worksheet B, column 3, lines 4 through 16) to total facility noncapital overhead costs (Worksheet B, column 18, line 101 less the sum of Worksheet B, columns 0 through 2, line 101). This proposed methodology assumes the ratio of total overhead benefit costs to total noncapital overhead costs is consistent among all four levels of care.

Comment: Another specific concern raised by the commenters was that there are inconsistencies in reporting medical supply and pharmacy costs on line 10 and line 14 of Worksheet A. They stated that some hospices use Worksheets A–1, A–2, A–3, and A–4 to report all or most of these costs whereas others use lines 10 and lines 14 and report costs as overhead costs. The commenters recommended that CMS look further into reporting all pharmacy and medical supply costs as direct patient care costs on future cost reports. The commenter stated that other acceptable cost reporting methods may be applicable; however, a Level 1 edit is not currently produced if costs are reported in one of the two acceptable locations.

Response: As described in the FY 2022 hospice proposed rule (86 FR 19717 through 19719), our proposed calculation to derive the hospice labor shares uses the sum of five categories of compensation costs. The estimated compensation costs related to medical supply and pharmacy costs would be reflected in the Other Patient Care Salaries, Overhead Salaries, and Overhead Benefits categories. We proposed that total costs for CHC be equal to Worksheet B, column 18, line 50, for RHC are equal to Worksheet B, column 18, line 51, for IRC would be equal to Worksheet B, column 18, line 52, and for GIP are equal to Worksheet B, column 18, line 53. These total costs would reflect medical supply and pharmacy costs when reported on Worksheet A line 10 and 14 or when reported on Worksheet A–1, A–2, A–3, and A–4. Therefore, we believe our proposed methodology captures these costs appropriately. However, we will consider this comment when requesting any future revisions to the Level 1 edits applied to the hospice cost report.

Comment: One commenter had concerns with the inconsistent reporting of certain types of overhead expenses among hospices. They stated in some instances, Medical Directors are employees and salaries would be reported; however, other hospices contract for this position. The commenter stated that the contracted payments for Medicare Directors are not included in the proposed calculation of overhead salaries. The commenter asked whether any consideration was made regarding this inconsistency or other common inconsistencies in the nature of the expenses.

Response: We appreciate the commenter's concern and conducted an additional review of our proposed methodology for appropriately capturing overhead costs in the labor shares.

As noted by the commenter, salaries and benefit costs for employed Medical Directors would be reported in Worksheet A, column 1, line 15 (salaries) and Worksheet B, column 3, line 15 (benefits), which are both included in our proposed methodology as these expenses are reported in overhead salaries and overhead benefits. As described in the proposed rule (86 FR 19718) and above, we include a proportion overhead salaries and overhead benefits in the compensation cost weights for each level of care.

However, after performing a detailed review of the calculation, we acknowledge that Medical Director contract labor costs would be reported in Worksheet A, column 2, line 15, which we do not include in the proposed compensation cost weight. In addition to Physician Administrative Services (line 15), we identified one additional overhead cost center where contract labor costs for patient care are reported and not reflected in the labor shares for each level of care: Nursing Administration (line 9). We believe these cost centers (Physician Administrative Services and Nursing Administration) are labor-intensive and vary with the local labor market and, thus, we believe contract labor costs for these services should be included in the labor shares for each level of care. Therefore, in response to public comment, we are revising our methodology for calculating overhead benefits attributable to each level of care. We are including in total facility overhead benefits those costs reported in Worksheet A, column 2, lines 9 and 15. A proportion of overhead benefit costs are allocated to each level of care using our methodology as stated above and in the proposed rule (86 FR 19718). This revision to our labor share methodology results in upward revisions to the proposed labor shares for each of the levels of care (between 0.6 percentage point and 1.1 percentage point). The labor shares showing the revised methodology are provided in Table 1.

f. Total Compensation Costs and Total Costs

To calculate the compensation costs for each provider, we proposed to then sum each of the costs estimated in steps (1) through (5) to derive total compensation costs for CHC, RHC, IRC, and GIP. We proposed that total costs

for CHC are equal to Worksheet B, column 18, line 50, for RHC are equal to Worksheet B, column 18, line 51, for IRC are equal to Worksheet B, column 18, line 52, and for GIP are equal to Worksheet B, column 18, line 53.

3. Methodology for Deriving Compensation Cost Weights

To derive the compensation cost weights for each level of care, we first proposed to begin with a sample of providers who met new Level I edit conditions that required freestanding hospices to fill out certain parts of their cost reports effective for freestanding hospice cost reports with a reporting period that ended on or after December 31, 2017.[3] Specifically, we required the following costs to be greater than zero: Fixed capital costs (Worksheet B, column 0, line 1), movable capital costs (Worksheet B, column 0, line 2), employee benefits (Worksheet B, column 0, line 3), administrative and general (Worksheet B, column 0, line 4), volunteer service coordination (Worksheet B, column 0, line 13), pharmacy and drugs charged to patients (sum of Worksheet B, column 0, line 14 and Worksheet A, column 7, line 42.50), registered nurse costs (Worksheet A, column 7, line 28), medical social service costs (Worksheet A, column 7, line 33), hospice aide and homemaker services costs (Worksheet A, column 7, line 37), and durable medical equipment (Worksheet A, column 7, line 38). Applying these Level I edits to the 2018 freestanding hospice MCRs resulted in 3,345 providers that passed the edits (four were excluded).

Then, for each level of care separately, we proposed to further trim the sample of MCRs. We outline our proposed trimming methodology using CHC as an example. Specifically, for CHC, we proposed that total CHC costs (Worksheet B, column 18, line 50) and CHC compensation costs to be greater than zero. We also proposed that CHC direct patient care salaries and contract labor costs per day is greater than 1. We also proposed to exclude those providers whose CHC compensation costs were greater than total CHC costs.

For the IRC and GIP compensation cost weights, we proposed to only use those MCRs from providers that provided inpatient services in their facility. Therefore, we proposed to exclude providers that reported costs greater than zero on Worksheet A–3, column 7, line 25 (Inpatient Care—Contracted) for IRC and Worksheet A–4, column 7, line 25 (Inpatient Care—Contracted) for GIP. The facilities that remained after this trim reported detailed direct patient care costs and other patient care costs for which we could then derive direct patient care salaries and other patient care salaries per the methodology described earlier.

Comment: One commenter stated that many of the hospice cost reports filed in 2018 failed to report contracted GIP days and contracted IRC care days on Worksheet S–1. Instead, they included all these days on line 23 and 33 of Worksheet S–1 but failed to report contracted days on line 40 and 41 of Worksheet S–1. The commenter stated that the failure to report contracted days on lines 40 and 41 would avoid a Level 1 edit if costs were not reported on Worksheets A–3 and A–4, line 25. The commenter stated that they understand that this reporting is inaccurate; however, there is no existing Level 1 edit that would catch it. The commenter questioned how CMS is determining that the inpatient costs are related solely to a freestanding inpatient unit on Worksheet A–4. The commenter claimed that if it is solely because no costs are reported on line 25, this assumption is in error. The commenter also claimed that if it is based on no days being reported as contracted on Worksheet S–1, this assumption is also in error. The commenter was concerned that costs—and accordingly labor component costs—are based on a small population with high risk of error.

One commenter stated that with only those cost reports from providers that have a hospice inpatient unit being used to determine the GIP and inpatient respite labor costs, they are concerned because one of their two affiliated hospices does have an inpatient unit, and yet they sometimes refer patients to contracted facilities for these levels of care as well. The commenter stated that it appears that the percentage of hospice cost reports used for determining GIP and respite total costs and labor-component costs is based on a small population of hospice providers with a significant risk of error; therefore, the commenter recommended that CMS rethink its approach for GIP and respite labor costs.

One commenter stated that their hospice utilizes general inpatient contracts, as they do not have our own facility. Thus, inpatient services on line 25 are not captured.

Response: We appreciate the commenters' concerns on the accuracy of the IRC and GIP cost data on the MCR. As stated in the FY 2022 Hospice proposed rule (86 FR 19718 through 19719) and above, for purposes of calculating the IRC and GIP compensation cost weights, we excluded providers that reported costs greater than zero on Worksheet A–3, column 7, line 25 (Inpatient Care—Contracted) for IRC and Worksheet A–4, column 7, line 25 (Inpatient Care—Contracted) for GIP. Then, for each level of care separately, we further trimmed the sample of cost reports. Specifically, for IRC, we required total IRC costs (Worksheet B, column 18, line 52) and IRC compensation costs to be greater than zero. We also required that IRC direct patient care salaries and contract labor costs per day would be greater than 1. We also excluded those providers whose IRC compensation costs were greater than total IRC costs. We then simultaneously removed those providers whose total IRC costs per day fall in the top and bottom one percent of total IRC costs per day for all IRC providers as well remove those providers whose compensation cost weight falls in the top and bottom five percent of compensation cost weights for all IRC providers.

We did not exclude providers based on the reporting of contracted inpatient days as reported on Worksheet S–1. In response to the public comment, we did test applying an additional edit that would exclude providers who reported contracted inpatient days on Worksheet S–1 as part of our basic trims. This excluded two providers and had no impact on the compensation cost weights for both IRC and GIP when rounded to a tenth of a percentage point. We encourage providers to report their cost report data accurately and timely.

Comment: Another specific concern stated by the commenters was that the determination of the labor share for GIP and IRC is based on Worksheet A–3 and A–4; however, any hospices reporting costs on line 25 (contracted services) were not included in the sample used for setting the labor share. The commenters recognize that the inclusion of any costs on line 25 would distort the labor component for these inpatient services; however, the commenters' experience indicates that most hospices with inpatient units also contract for some inpatient days with outside providers for a variety of reasons. The commenters stated that many of these hospices providers have some of the best accounting records in the industry and the proposed methodology for calculating the labor components eliminates the costs of these facilities from consideration. The commenters stated that the proposed rule indicates

[3] Medicare Department of Health and Human Services (DHHS) Provider Reimbursement Manual—Part 2, Provider Cost Reporting Forms and Instructions, Chapter 43, Form CMS–1984–14. April 13, 2018. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R3P243.pdf.*

that 20 percent of IRC and 28 percent of GIP providers were included in the calculation. The commenters requested that CMS provide the final number of hospices with inpatient units that were used in the calculation of the labor components for both levels of care, and the total universe of IRC and GIP providers. One commenter also stated that they were interested in how the percentage of hospices that operate inpatient facilities can be increased and all costs, including contracted costs, can be included.

Response: The proposed hospice labor shares for the IRC level of care and GIC level of care (after trimming for outliers) is based on costs for 416 and 295 providers, respectively. These providers reflected approximately 53,000 IRP days of which about 47,000 were Medicare and approximately 136,000 GIC days of which about 108,000 were Medicare. Although this a smaller sample of providers than used for the other proposed labor shares for RHC (2,919 providers) and CHC (1,240 providers), we believe this is a technical improvement to the current labor shares that were primarily based on skilled nursing facility costs from the early 1980s. Our proposed methodology utilizes freestanding hospice cost report data reflecting the skilled hospice care provided in 2018 and the associated direct and indirect costs required to provide these services in 2018. We encourage all providers to report the cost report data accurately and timely so we can include more providers' cost report data in the labor share calculations. We will monitor the cost report data to determine whether the proposed updated labor shares are still appropriate.

Comment: Another specific concern raised by commenters was that the cost reports should be amended to allow for a greater breakdown of costs for contracted vs. hospice-administered inpatient services. Specifically, one commenter stated that when the cost report was revised in 2014, some industry experts recommended that CMS develop two separate worksheets for IRC and GIC. The first worksheet would represent costs associated with freestanding units operated by the hospice and the second worksheet would be for costs associated with contracted services. The commenter stated CMS should see value in potentially adding these worksheets if, in fact, it intends to calculate labor components for these levels of care based on cost report data going forward. The commenter also recommended that CMS could add a question to the cost report asking whether the hospice operates a freestanding inpatient and/or inpatient respite care facility. A ''no'' answer would require reporting contracted days and contracted costs or produce a Level 1 edit. The commenter stated that this would better allow CMS to isolate the costs of those facilities that truly operate an inpatient unit.

One commenter requested that CMS work with stakeholders and the hospice community to identify the best approaches, and separate worksheets, for GIP and inpatient respite costs, including both hospices that operate a freestanding facility and hospices that have contracted beds.

Response: We appreciate the commenters request for future changes to the hospice cost report to allow us to better isolate costs of those facilities that operate an inpatient unit. As stated above, we believe that our current method for calculating the IRC and GIP compensation cost weights provides an accurate measure of the labor shares for these levels of care. We will consider this comment when working on any future modifications to the hospice cost report. We will also continue to monitor the hospice labor shares as more recent data become available. We note that any future revisions to the hospice labor shares will be proposed and subject to public comments in future rulemaking.

Finally, as proposed, to derive the compensation cost weights for each level of care for each provider, we divide compensation costs for each level of care by total costs for each level of care. We then trim the data for each level of care separately to remove outliers. Following our example for CHC, we simultaneously remove those providers whose total CHC costs per day fall in the top and bottom one percent of total CHC costs per day for all CHC providers as well remove those providers whose compensation cost weight falls in the top and bottom five percent of compensation cost weights for all CHC providers. We then sum the CHC compensation costs and total CHC costs of the remaining providers, yielding a proposed compensation cost weight for CHC.

Since we limited our sample for IRC and GIP compensation cost weights to those hospices providing inpatient services in their facility, we conducted sensitivity analysis to test for the representative of this sample by reweighting compensation cost weights using data from the universe of freestanding providers that reported either IRC or GIP total costs. For example, we calculated reweighted compensation cost weights by ownership-type (proprietary, government and nonprofit), by size (based on RHC days) and by region. Our reweighted compensation cost weights for IRC and GIP were similar (less than one percentage point in absolute terms) to our proposed compensation cost weights for IRC and GIP (as shown in Table 1) and, therefore, we believe our sample is representative of freestanding hospices providing inpatient hospice care.

Comment: One commenter requested that clarification as to how CMS will adjust the labor share if certain types of hospices are found to provide more services and thus, likely have a larger labor share but contribute fewer cost reports.

Response: As described in the FY 2022 Hospice proposed rule (86 FR 17919) and above, the proposed compensation cost weights are equal to the sum of the compensation costs divided by the sum of the total costs for those remaining providers after trimming for outliers. Therefore, hospice providers with larger costs (reflecting larger utilization) would have a larger weight in the proposed labor shares. We would note that Medicare days, in aggregate, account for over 80 percent of total facility days. As stated previously, we will continue to monitor the labor shares over time and propose revisions to these shares to reflect a more recent cost structure and mix of providers.

Comment: One commenter stated that given the inherent differences in the provision of the hospice benefit between different types of hospice providers, they would recommend that CMS monitor any significant disparities in the distribution of labor and non-labor inputs across the hospice industry by program characteristics. The commenter stated that they would become concerned, for instance, if data indicates that some providers offer significantly fewer hours of professional interdisciplinary team (IDT) care yet make up a disproportionate percentage of providers filing cost reports. This could lead to unintended negative consequences for those providers fulfilling the true spirit and intent of the benefit. Put simply, if cost reports and other data indicate a widening gap in labor inputs between for-profit and not-for-profit providers, then CMS should investigate this trend further.

Response: We appreciate the commenter's concern regarding labor hours provided by type of facility. As we are able to obtain more recent cost report data, we will monitor the labor shares by ownership-type over time.

Comment: One commenter stated that if the labor shares are going to have a greater weight on CHC, hospices should

be allowed to use it effectively. The commenter recommended that the current continuous care timeframe change from midnight to midnight to a new time frame of noon to noon and that visits from other providers such as chaplains and home health aides count toward the continuous care timeframe.

Response: While this comment is outside the scope of this rule as we did not make any proposals relating to our CHC policy, we thank the commenter for their recommendations and will take them under consideration for future rulemaking.

Final Decision: In summary, in response to public comments, we are adopting the revised hospice labor shares calculated as we proposed with a slight modification to the methodology to derive the overhead benefit calculations as described previously. Table 1 provides the finalized labor share for each level of care based on the compensation cost weights we derived using our revised methodology. As we proposed, the labor shares are rounded to three decimal places consistent with the labor shares used in other Prospective Payment Systems (PPS) (such as the inpatient prospective payment system (IPPS) and the Home Health Agency PPS). The revised labor shares will be implemented in a budget neutral manner through the use of labor share standardization factors.

TABLE 1: Final, Proposed, and Current Labor shares by Level of Care

	Final FY 2022 Labor shares	Proposed FY 2022 Labor shares	Current Labor shares
Continuous Home Care	75.2%	74.6%	68.71%
Routine Home Care	66.0%	64.7%	68.71%
Inpatient Respite Care	61.0%	60.1%	54.13%
General Inpatient Care	63.5%	62.8%	64.01%

We also received six comments on the use of the labor share standardization factor including hospices, national industry associations. A summary of these comments and our responses to those comments appear below:

Comment: A few commenters requested more information regarding the labor share standardization factor; specifically, its purpose, and any anticipated future use of the factor.

Response: The labor share standardization factor is applied to the FY 2022 hospice payment rates so that the aggregate payments do not increase or decrease due to changes in the labor share values. We proposed to implement the proposed hospice labor shares in a budget neutral manner which is consistent with our policy of implementing updates to the hospice wage index in a budget neutral manner as well as updates in other perspective payment systems such as the annual recalibration of the case-mix weights in home health and updates to the home health wage index. In order to calculate the labor share standardization factor, we simulate total payments using FY 2020 hospice utilization claims data with the FY 2022 hospice wage index and the current labor shares and compare it to our simulation of total payments using the FY 2022 hospice wage index with the final revised labor shares. By dividing total payments for each level of care (RHC days 1 through 60, RHC days 61+, CHC, IRC, and GIP) using the FY 2022 wage index, current labor shares and payment rates for each level of care by the total payments for each level of care using the final revised labor shares and FY 2022 wage index and payment.

Final Decision: We are finalizing the proposal to implement the hospice labor shares in a budget neutral manner through the use of the labor share standardization factors, so that the aggregate payments do not increase or decrease due to changes in the labor share values.

C. FY 2022 Hospice Wage Index and Rate Update

1. FY 2022 Hospice Wage Index

The hospice wage index is used to adjust payment rates for hospices under the Medicare program to reflect local differences in area wage levels, based on the location where services are furnished. The hospice wage index utilizes the wage adjustment factors used by the Secretary for purposes of section 1886(d)(3)(E) of the Act for hospital wage adjustments. Our regulations at § 418.306(c) require each labor market to be established using the most current hospital wage data available, including any changes made by the Office of Management and Budget (OMB) to the Metropolitan Statistical Areas (MSAs) definitions.

In general, 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 March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017 and July 1, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area, one new component of an existing Combined Statistical Are and changes to New England City and Town Area (NECTA) delineations. In the FY 2021 Hospice Wage Index final rule (85 FR 47070) we stated that if appropriate, we would propose any updates from OMB Bulletin No. 20–01 in future rulemaking. After reviewing OMB Bulletin No. 20–01, we have determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare wage index for FY 2022. Specifically, the updates consisted of changes to NECTA delineations and the redesignation of a single rural county into a newly created Micropolitan Statistical Area. The Medicare wage index does not utilize NECTA definitions, and, as most recently discussed in the FY 2021 Hospice Wage Index final rule (85 FR 47070), we include hospitals located in Micropolitan Statistical areas in each state's rural wage index. Therefore, while we proposed to adopt the updates set forth in OMB Bulletin No. 20–01 consistent with our longstanding policy of adopting OMB delineation updates, we note that specific wage index updates would not be necessary for FY 2022 as a result of adopting these OMB updates. In other words, these OMB updates would not affect any geographic areas for purposes of the wage index calculation for FY 2022.

In the FY 2020 Hospice Wage Index final rule (84 FR 38484), we finalized the proposal to use the current FY's hospital wage index data to calculate the hospice wage index values. In the FY 2021 Hospice Wage Index final rule (85 FR 47070), we finalized the proposal to adopt the revised OMB delineations with a 5 percent cap on wage index decreases, where the estimated reduction in a geographic area's wage index would be capped at 5 percent in FY 2021 and no cap would be applied to wage index decreases for the second year (FY 2022). For FY 2022, the final hospice wage index will be based on the FY 2022 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2017 and before October 1, 2018 (FY 2018 cost report data). The final FY 2022 hospice wage index will not include a cap on wage index decreases and would not take into account any geographic reclassification of hospitals, including those in accordance with section 1886(d)(8)(B) or 1886(d)(10) of the Act. The appropriate wage index value is applied to the labor portion of the hospice payment rate based on the geographic area in which the beneficiary resides when receiving RHC or CHC. The appropriate wage index value is applied to the labor portion of the payment rate based on the geographic location of the facility for beneficiaries receiving GIP or IRC.

In the FY 2006 Hospice Wage Index final rule (70 FR 45135), we adopted the policy that, for urban labor markets without a hospital from which hospital wage index data could be derived, all of the Core-Based Statistical Areas (CBSAs) within the state would be used to calculate a statewide urban average pre-floor, pre-reclassified hospital wage index value to use as a reasonable proxy for these areas. For FY 2022, the only CBSA without a hospital from which hospital wage data can be derived is 25980, Hinesville-Fort Stewart, Georgia. The FY 2022 final wage index value for Hinesville-Fort Stewart, Georgia is 0.8635.

There exist some geographic areas where there were no hospitals, and thus, no hospital wage data on which to base the calculation of the hospice wage index. In the FY 2008 Hospice Wage Index final rule (72 FR 50217 through 50218), we implemented a methodology to update the hospice wage index for rural areas without hospital wage data. In cases where there was a rural area without rural hospital wage data, we use the average pre-floor, pre-reclassified hospital wage index data from all contiguous CBSAs, to represent a reasonable proxy for the rural area. The term ''contiguous'' means sharing a border (72 FR 50217). Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we would not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we would continue to use the most recent wage index previously available for that area. For FY 2022, we proposed to continue to use the most recent pre-floor, pre-reclassified hospital wage index value available for Puerto Rico, which is 0.4047, subsequently adjusted by the hospice floor.

As described in the August 8, 1997 Hospice Wage Index final rule (62 FR 42860), the pre-floor and pre-reclassified hospital wage index is used as the raw wage index for the hospice benefit. These raw wage index values are subject to application of the hospice floor to compute the hospice wage index used to determine payments to hospices. As previously discussed, the adjusted pre-floor, pre-reclassified hospital wage index values below 0.8 will be further adjusted by a 15 percent increase subject to a maximum wage index value of 0.8. For example, if County A has a pre-floor, pre-reclassified hospital wage index value of 0.3994, we would multiply 0.3994 by 1.15, which equals 0.4593. Since 0.4593 is not greater than 0.8, then County A's hospice wage index would be 0.4593. In another example, if County B has a pre-floor, pre-reclassified hospital wage index value of 0.7440, we would multiply 0.7440 by 1.15, which equals 0.8556. Because 0.8556 is greater than 0.8, County B's hospice wage index would be 0.8.

The final hospice wage index applicable for FY 2022 (October 1, 2021 through September 30, 2022) is available on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index.html*.

We received seven comments on the proposed FY 2022 hospice wage index from various stakeholders including hospices, and national industry associations. A summary of these comments and our responses to those comments appear below:

Comment: One commenter expressed concern that hospices in Montgomery County, Maryland are at a long-term competitive disadvantage due to what they refer to as a Medicare hospice Federal payment inequity involving CBSAs specifically when Metropolitan Divisions are present. The commenter stated that that hospices in Montgomery County should be reimbursed at the

same level as hospices in the Washington, DC area because Montgomery County has a similar cost of living and cost of doing business compared to Washington, DC and shares the same labor market when competing for labor. This commenter recommended several solutions to resolve this issue, including applying the outmigration hospital adjustment which is a hospital wage adjustment based on commuting patterns referenced in section 505 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 to the hospice wage index; allowing hospices serving patients in MSAs that are large enough to be subdivided into metropolitan divisions to opt for the higher wage index valuation within the MSA's respective CBSAs or providing a 1-year limited increase in hospice wage index payments in the Montgomery County Metropolitan Divisions as a short-term fix to this problem.

Response: We thank the commenter for these recommendations. However, we continue to believe that the OMB's geographic area delineations represent a useful proxy for differentiating between labor markets and that the geographic area delineations are appropriate for use in determining Medicare hospice payments. Additionally, we do not believe that we have the authority to apply the outmigration hospital adjustment to the hospice wage index because it is specific to the commuting patterns of hospital employees. We also do not believe it would be appropriate to allow hospices to opt for or be assigned a higher CBSA designation based on subdivided metropolitan divisions. Finally, in the FY 2021 Hospice Wage Index and Payment Rate Update final rule (85 FR 47079), we finalized a 1-year transition 5 percent cap on wage index decreases for fiscal year (FY) 2021 only. We believe that this transition was sufficient in order to mitigate the resulting short-term instability and negative impacts on certain providers after the implementation of the new OMB labor market delineations. We do not believe that a 1-year limited increase in hospice wage index payments for hospices specifically in the Montgomery County Metropolitan Divisions is appropriate at this time.

Based on the OMB's current delineations, Montgomery County belongs in a separate CBSA from the areas defined in the Washington-Arlington-Alexandria, DC-VA CBSA. Unlike inpatient prospective payment system (IPPS) hospitals, inpatient rehabilitation facilities (IRFs), and skilled nursing facilities (SNFs), where each provider uses a single CBSA, hospice agencies may be reimbursed based on more than one wage index. Payments are based upon the location of the beneficiary for routine and continuous home care or the location of the facility for respite and general inpatient care. Hospices in Montgomery County, Maryland may provide RHC and CHC to patients in the ''Washington-Arlington-Alexandria, DC-VA'' CBSA and to patients in the ''Baltimore-Columbia-Towson, Maryland'' CBSA. We have used CBSAs for determining hospice payments since FY 2006. Additionally, other provider types, such as IPPS hospitals, home health agencies (HHAs), SNFs, IRFs, and the dialysis facilities all use CBSAs to define their labor market areas. We believe that using the most current OMB delineations provides a more accurate representation of geographic variation in wage levels and do not believe it would be appropriate to allow hospices to be assigned a higher CBSA designation or to allow 1-year limited increase in hospice wage index payments for hospices only in the Montgomery County Metropolitan Divisions.

Comment: One commenter recommended CMS institute a policy that no hospice be paid below the rural floor for their state, allow hospices and other post-acute providers to utilize a reclassification board similar to hospitals, and consider working with the Congress on policies to reform the wage index such as revisiting MedPAC's 2007 proposal which recommended that the Congress repeal the existing hospital wage index statute, including reclassifications and exceptions, and give the Secretary authority to establish new wage index systems. In chapter 6 of the June 2007 Report to Congress, MedPAC recommended the new wage index should: Use wage data from all employers and industry-specific occupational weights, adjust for geographic differences in the ratio of benefits to wages, adjust at the county level and smooth large differences between counties, and be implemented so that large changes in wage index values are phased in over a transition period.[4] Another commenter recommended that CMS develop and implement a wage index model that is consistent across all provider types so that all types of providers have a level playing field from which to compete for personnel.

Response: We appreciate the commenters' recommendations; however, these comments are outside the scope of the proposed rule. Any changes to the way we adjust hospice payments to account for geographic wage differences, beyond the wage index proposals discussed in the FY 2022 Hospice Wage Index and Rate Update proposed rule, would have to go through notice and comment rulemaking. While CMS and other stakeholders have explored potential alternatives to the current CBSA-based labor market system, no consensus has been achieved regarding how best to implement a replacement system.

Additionally, the regulations that govern hospice reimbursement do not provide a mechanism for allowing hospices to seek geographic reclassification or to utilize the rural floor provisions that exist for IPPS hospitals. The reclassification provision found in section 1886(d)(10) of the Act is specific to hospitals. Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that state. This rural floor provision is also specific to hospitals. Because the reclassification provision and the hospital rural floor applies only to hospitals, and not to hospices, we continue to believe the use of the pre-floor and pre-reclassified hospital wage index results in the most appropriate adjustment to the labor portion of the hospice payment rates. We remind stakeholders that the hospice wage index does include the hospice floor which is applicable to all CBSAs, both rural and urban. Pre-floor, pre-reclassified hospital wage index values below 0.8 are adjusted by a 15 percent increase subject to a maximum wage index value of 0.8.

Comment: A few commenters stated that providers should be protected against substantial payment reductions due to dramatic reductions in wage index values from one year to the next. One commenter recommended that CMS maintain the 5 percent cap that was put in place for FY 2021 or lower the cap to 3 percent to protect hospice providers who are already operating with negative or razor thin operating margins. Another commenter expressed concern regarding the adoption of the New Brunswick-Lakewood, NJ CBSA and recommended CMS adopt a transition policy that holds the FY 2022 and FY 2023 wage index for all affected facilities harmless from any reduction relative to their FY 2021 wage index.

[4] Report to Congress, Promoting Greater Efficiency in Medicare. MedPAC. June 2007. *http://www.medpac.gov/docs/default-source/reports/Jun07_EntireReport.pdf.*

Response: We appreciate the concerns sent in by the commenters regarding the impact of wages index changes from year to year as well as the concerns from providers who have been impacted by the implementation of the New Brunswick-Lakewood, NJ CBSA designation. While, we understand the commenters' concern regarding the potential financial impact, we believe that the OMB delineations for Metropolitan and Micropolitan Statistical Areas are appropriate for use in accounting for wage area differences and that the values computed under the delineations result in more appropriate payments to providers by more accurately accounting for and reflecting the differences in area wage levels. In the FY 2021 Hospice Wage Index and Payment Rate Update final rule (85 FR 47079), we finalized a 1-year transition for fiscal year (FY) 2021 only, to mitigate the resulting short-term instability and negative impacts on certain providers and to provide time for providers to adjust to their new labor market delineations. We believe that the 1-year 5 percent cap transitional policy provided for FY 2021 was an adequate safeguard against any significant payment reductions, allowed for sufficient time to make operational changes for future fiscal years, and provided a reasonable balance between mitigating some short-term instability in hospice payments and improving the accuracy of the payment adjustment for differences in area wage levels.

We note that certain changes to wage index policy may significantly affect Medicare payments. These changes may arise from revisions to the OMB delineations of statistical areas resulting from the decennial census data, periodic updates to the OMB delineations in the years between the decennial censuses, or other wage index policy changes. While we consider how best to address these potential scenarios in a consistent and thoughtful manner, we reiterate that our policy principles with regard to the wage index include generally using the most current data and information available and providing that data and information, as well as any approaches to addressing any significant effects on Medicare payments resulting from these potential scenarios, in notice and comment rulemaking.

Final Decision: We are finalizing our proposal to use the FY 2022 pre-floor, pre-reclassified hospital wage index data as the basis for the FY 2022 hospice wage index. The wage index applicable for FY 2022 is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Wage-Index*. The hospice wage index for FY 2022 is effective October 1, 2021 through September 30, 2022.

2. FY 2022 Hospice Payment Update Percentage

Section 4441(a) of the BBA (Pub. L. 105–33) amended section 1814(i)(1)(C)(ii)(VI) of the Act to establish updates to hospice rates for FYs 1998 through 2002. Hospice rates were to be updated by a factor equal to the inpatient hospital market basket percentage increase set out under section 1886(b)(3)(B)(iii) of the Act, minus 1 percentage point. Payment rates for FYs since 2002 have been updated according to section 1814(i)(1)(C)(ii)(VII) of the Act, which states that the update to the payment rates for subsequent FYs must be the inpatient market basket percentage increase for that FY. CMS currently uses 2014-based IPPS operating and capital market baskets to update the market basket percentage. In the FY 2022 IPPS proposed rule [5] we proposed to rebase and revise the IPPS market baskets to reflect a 2018 base year. We refer stakeholders to the FY 2022 IPPS proposed rule for further information (86 FR 25416 through 25428).

Section 3401(g) of the Affordable Care Act mandated that, starting with FY 2013 (and in subsequent FYs), the hospice payment update percentage would be annually reduced by changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. 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).

In the FY 2022 Hospice Wage Index and Payment Rate Update proposed rule (86 FR 19720), we proposed the market basket percentage increase of 2.5 percent for FY 2022 using the most current estimate of the inpatient hospital market basket (based on IHS Global Inc.'s fourth-quarter 2020 forecast with historical data through the third quarter 2020). Due to the requirements at sections 1886(b)(3)(B)(xi)(II) and 1814(i)(1)(C)(v) of the Act, the proposed inpatient hospital market basket update for FY 2022 of 2.5 percent was reduced by a productivity adjustment as mandated by Affordable Care Act (estimated in the proposed rule to be 0.2 percentage point for FY 2022). Therefore, the proposed hospice payment update percentage for FY 2022 was 2.3 percent.

We also stated if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, more recent estimates of the inpatient hospital market basket update and/or productivity adjustment), we would use such data to determine the hospice payment update percentage for FY 2022 in the final rule. For this final rule, based on IHS Global Inc.'s (IGI) second quarter 2021 forecast with historical data through the first quarter 2021 of the inpatient hospital market basket update, the market basket percentage increase for FY 2022 is 2.7 percent. The productivity adjustment for FY 2022, based on IGI's second quarter 2021 forecast, is 0.7 percent. Therefore, the hospice payment update percentage for FY 2022, based on more recent data, is 2.0 percent.

Currently, the labor portion of the hospice payment rates are as follows: For RHC, 68.71 percent; for CHC, 68.71 percent; for GIP, 64.01 percent; and for IRC, 54.13 percent. As discussed in section III.B of this rule, we are finalizing to rebase and revise the labor shares for CHC, RHC, GIP and IRC using MCR data for freestanding hospices (CMS Form 1984–14, OMB Control Number 0938–0758) for 2018. We are finalizing the labor portion of the payment rates to be for CHC, 75.2 percent; for RHC, 66.0 percent; for GIP, 63.5 percent; and for IRC, 61.0 percent. The non-labor portion is equal to 100 percent minus the labor portion for each level of care. Therefore, we are finalizing the non-labor portion of the payment rates to be as follows: For CHC, 24.8 percent; RHC, 34 percent; for GIP, 36.5 percent; and For IRC, 39.0 percent.

Comment: We received seven comments in support of the proposed hospice update percentage of 2.3 percent. However, in its comment, MedPAC ''concluded that the aggregate level of payments could be reduced and would still be sufficient to cover hospice providers' costs and preserve beneficiaries' access to care.'' Therefore, MedPAC recommended a zero percent update for FY 2022 for all hospice providers.

Response: We appreciate the support from commenters as well as MedPAC's concerns. However, section 1814(i)(1)(C)(iii) of the Act requires the Secretary, for years subsequent to the first fiscal year in which payment revisions described in paragraph (6)(D) are implemented, to update the payment rates by the market basket percentage increase (as defined in section 1886(b)(3)(B)(iii)) of the Act for the

[5] IPPS Regulations and Notices. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices.*

fiscal year; section 1814(i)(1)(C)(iv)(I) of the Act requires that subsequent to such increase, the payment rates be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Final Decision: We are finalizing the hospice payment update percentage of 2.0 percent for FY 2022. Based on IHS Global, Inc.'s more recent forecast of the inpatient hospital market basket update and the productivity adjustment, the hospice payment update percentage for FY 2022 will be 2.0 percent for hospices that submit the required quality data and 0.0 percent (FY 2022 hospice payment update of 2.0 percent minus 2.0 percentage points) for hospices that do not submit the required data.

3. FY 2022 Hospice Payment Rates

There are four payment categories that are distinguished by the location and intensity of the hospice services provided. The base payments are adjusted for geographic differences in wages by multiplying the labor share, which varies by category, of each base rate by the applicable hospice wage index. A hospice is paid the RHC rate for each day the beneficiary is enrolled in hospice, unless the hospice provides CHC, IRC, or GIP. CHC is provided during a period of patient crisis to maintain the patient at home; IRC is short-term care to allow the usual caregiver to rest and be relieved from caregiving; and GIP is to treat symptoms that cannot be managed in another setting.

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47172), we implemented two different RHC payment rates, one RHC rate for the first 60 days and a second RHC rate for days 61 and beyond. In addition, in that final rule, we implemented a SIA payment for RHC when direct patient care is provided by an RN or social worker during the last 7 days of the beneficiary's life. The SIA payment is equal to the CHC hourly rate multiplied by the hours of nursing or social work provided (up to 4 hours total) that occurred on the day of service, if certain criteria are met. To maintain budget neutrality, as required under section 1814(i)(6)(D)(ii) of the Act, the new RHC rates were adjusted by a service intensity add-on budget neutrality factor (SBNF). The SBNF is used to reduce the overall RHC rate to ensure that SIA payments are budget-neutral. At the beginning of every fiscal year, SIA utilization is compared to the prior year in order calculate a budget neutrality adjustment.

In the FY 2017 Hospice Wage Index and Rate Update final rule (81 FR 52156), we initiated a policy of applying a wage index standardization factor to hospice payments to eliminate the aggregate effect of annual variations in hospital wage data. Typically, the wage index standardization factor is calculated using the most recent, complete hospice claims data available. However, due to the COVID–19 PHE, we looked at using the previous fiscal year's hospice claims data (FY 2019) to determine if there were significant differences between utilizing 2019 and 2020 claims data. The difference between using FY 2019 and FY 2020 hospice claims data was minimal. Therefore, we will continue our practice of using the most recent, complete hospice claims data available; that is, we used FY 2020 claims data for the FY 2022 payment rate updates.

To calculate the wage index standardization factor, we simulate total payments using FY 2020 hospice utilization claims data with the FY 2021 wage index (pre-floor, pre-reclassified hospital wage index with the hospice floor, and a 5 percent cap on wage index decreases) and FY 2021 payment rates (that include the current labor shares) and compare it to our simulation of total payments using the FY 2022 hospice wage index (with hospice floor, without the 5 percent cap on wage index decreases) and FY 2021 payment rates (that include the current labor shares). By dividing total payments for each level of care (RHC days 1 through 60, RHC days 61+, CHC, IRC, and GIP) using the FY 2021 wage index and payment rates for each level of care by the total payments using the FY 2022 wage index and FY 2021 payment rates, we obtain a wage index standardization factor for each level of care. As stated above, in order to calculate the labor share standardization factor, we simulate total payments using FY 2020 hospice utilization claims data with the FY 2022 hospice wage index and the current labor shares and compare it to our simulation of total payments using the FY 2022 hospice wage index with the final revised labor shares. By dividing total payments for each level of care (RHC days 1 through 60, RHC days 61+, CHC, IRC, and GIP) using the current labor shares and FY 2022 wage index and payment rates for each level of care by the total payments for each level of care using the final revised labor shares and FY 2022 wage index and payment rates for each level of care, we obtain a labor share standardization factor for each level of care. The wage index and labor share standardization factors for each level of care are shown in the Tables 2 and 3.

The FY 2022 RHC rates are shown in Table 2. The FY 2022 payment rates for CHC, IRC, and GIP are shown in Table 3.

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TABLE 2: FY 2022 Hospice RHC Payment Rates

Code	Description	FY 2021 payment rates	SIA Budget neutrality factor	Wage index standardization factor	Labor share standardization factor	FY 2022 hospice payment update	FY 2022 payment rates
651	Routine Home Care (days 1-60)	$199.25	1.0003	1.001	0.9995	1.02	$203.40
651	Routine Home Care (days 61+)	$157.49	1.0005	1.0009	0.9992	1.02	$160.74

TABLE 3: FY 2022 Hospice CHC, IRC, and GIP Payment Rates

Code	Description	FY 2021 payment rates	Wage index standardization factor	Labor share standardization factor	FY 2022 hospice payment update	FY 2022 payment rates
652	Continuous Home Care Full Rate = 24 hours of care.	$1,432.41	1.0004	1.0006	1.02	$1,462.52 ($60.94 per hour)
655	Inpatient Respite Care	$461.09	1.0014	1.0059	1.02	$473.75
656	General Inpatient Care	$1,045.66	1.0019	0.9997	1.02	$1,068.28

Sections 1814(i)(5)(A) through (C) of the Act require that hospices submit quality data, based on measures to be specified by the Secretary. In the FY 2012 Hospice Wage Index and Rate Update final rule (76 FR 47320 through 47324), we implemented a HQRP as required by those sections. Hospices were required to begin collecting quality data in October 2012, and submit that quality data in 2013. Section 1814(i)(5)(A)(i) of the Act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements with respect to that FY. The FY 2022 rates for hospices that do not submit the required quality data would be updated by the FY 2022 hospice payment update percentage of 2.0 percent minus 2 percentage points. These rates are shown in Tables 4 and 5.

TABLE 4: FY 2022 Hospice RHC Payment Rates for Hospices That DO NOT Submit the Required Quality Data-

Code	Description	FY 2021 payment rates	SIA Budget neutrality factor	Wage index standardization factor	Labor share standardization factor	FY 2022 hospice payment update minus 2 percentage points = +0.0%	FY 2022 payment rates
651	Routine Home Care (days 1-60)	$199.25	1.0003	1.001	0.9995	1.00	$199.41
651	Routine Home Care (days 61+)	$157.49	1.0005	1.0009	0.9992	1.00	$157.58

TABLE 5: FY 2022 Hospice CHC, IRC, and GIP Payment Rates for Hospices That DO NOT Submit the Required Quality Data-

Code	Description	FY 2021 payment rates	Wage index standardization factor	Labor share standardization factor	FY 2022 hospice payment update minus 2 percentage points = +0.0%	FY 2022 payment rates
652	Continuous Home Care Full Rate = 24 hours of care.	$1,432.41	1.0004	1.0006	1.00	$1433.84 ($59.74 per hour)
655	Inpatient Respite Care	$461.09	1.0014	1.0059	1.00	$464.46
656	General Inpatient Care	$1,045.66	1.0019	0.9997	1.00	$1,047.33

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Final Decision: We are implementing the updates to hospice payment rates as discussed in the proposed rule.

4. Hospice Cap Amount for FY 2022

As discussed in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47183), we implemented changes mandated by the IMPACT Act of 2014 (Pub. L. 113–185). Specifically, the IMPACT Act requires that, for accounting years that end after September 30, 2016 and before October 1, 2025, the hospice cap be updated by the hospice payment update percentage rather than using the CPI–U. Division CC, section 404 of the CAA 2021 has extended the accounting years impacted by the adjustment made to the hospice cap calculation until 2030. Therefore, for accounting years that end after September 30, 2016 and before October 1, 2030, the hospice cap amount is updated by the hospice payment update percentage rather than using the CPI–U. As a result of the changes mandated by Division CC, section 404 of the CAA 2021, we proposed conforming regulation text changes at § 418.309 to reflect the new language added to section 1814(i)(2)(B) of the Act.

The hospice cap amount for the FY 2022 cap year will be $31,297.61, which is equal to the FY 2021 cap amount ($30,683.93) updated by the FY 2022 hospice payment update percentage of 2.0 percent.

Comment: Generally, commenters supported the update to the cap amount. We received a comment indicating some hospice agencies never hit the cap amount and recommend for CMS to utilize available claims and quality data to target hospices with questionable practices to avoid exceeding the cap amount.

Response: We appreciate the concern and recommendation. We encourage those who have concerns about fraud, waste, or abuse to report these to CMS Center for Program Integrity. Resources can be found at *https://www.cms.gov/About-CMS/Components/CPI.*

Comment: MedPAC recommended the hospice cap amount be reduced by 20 percent as a way to focus payment reductions on providers with particularly high margins. MedPAC also recommended wage adjusting the hospice cap amount to make it more equitable across providers.

Response: We appreciate MedPAC's comments; however, we are required by law to update the hospice cap amount from the preceding year by the hospice payment update percentage, in accordance with section 1814(i)(2)(B)(ii) of the Act. Therefore, we do not have the statutory authority to reduce the aggregate cap amount nor the statutory authority to wage-adjust the cap amount.

Final Decision: We are finalizing the update to the hospice cap amount for FY 2022 in accordance with statutorily-mandated requirements as well as the conforming regulation text changes at § 418.309.

D. Clarifying Regulation Text Changes for the Hospice Election Statement Addendum

In the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38484), we finalized modifications to the hospice election statement content requirements at § 418.24(b) to increase coverage transparency for patients under a hospice election. These changes included a new condition for payment requiring a hospice, upon request, to provide the beneficiary (or representative) an election statement addendum (hereafter called ''the addendum'') outlining the items, services, and drugs that the hospice has determined are unrelated to the terminal illness and related conditions. We stated in the final rule that the addendum is intended to complement the Hospice Conditions of Participation (CoPs) at § 418.52(c)(7) and (8), which require hospices to verbally inform beneficiaries, at the time of hospice election, of the services covered under the Medicare hospice benefit, as well as the limitations of such services (84 FR 38509). The requirements at §§ 418.24(b) and 418.52(a) ensure that beneficiaries are aware of any items, services, or drugs they would have to seek outside of the benefit, as well as their potential out-of-pocket costs for hospice care, such as co-payments and/or coinsurance.

Section 418.24(c) sets forth the elements that must be included on the addendum:

1. The addendum must be titled ''Patient Notification of Hospice Non-Covered Items, Services, and Drugs'';
2. Name of the hospice;
3. Beneficiary's name and hospice medical record identifier;
4. Identification of the beneficiary's terminal illness and related conditions;
5. A list of the beneficiary's current diagnoses/conditions present on

hospice admission (or upon plan of care update, as applicable) and the associated items, services, and drugs, not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions;

6. A written clinical explanation, in language the beneficiary and his or her representative can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the terminal illness and related conditions and not needed for pain or symptom management. This clinical explanation must be accompanied by a general statement that the decision as to what conditions, items, services, or drugs are unrelated is made for each individual patient, and that the beneficiary should share this clinical explanation with other health care providers from which he or she seeks services unrelated to his or her terminal illness and related conditions;

7. References to any relevant clinical practice, policy, or coverage guidelines;

8. Information on the following:

a. Purpose of the addendum

b. patient's right to immediate advocacy

9. Name and signature of the Medicare hospice beneficiary (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily the beneficiary's agreement with the hospice's determinations.

The hospice is required to furnish the addendum in writing in an accessible format, so the beneficiary (or representative) can understand the information provided, make treatment decisions based on that information, and share such information with non-hospice providers rendering un-related items and services to the beneficiary. Therefore, the format of the addendum must be usable for the beneficiary and/or representative. Although we stated in the FY 2020 Hospice Wage Index and Payment Rate Update that hospices may develop their own election statement addendum (84 FR 38507), we posted a modified model election statement and addendum on the Hospice web page,[6] along with the publication of the FY 2021 Hospice Wage Index and Payment Rate Update final rule (85 FR 47070). The intent was to provide an illustrative example so hospices can modify and develop their own forms to meet the content requirements. In the FY 2021 Hospice Wage Index and Payment Rate Update final rule, we stated that most often we would expect the addendum would be in a hard copy format the beneficiary or representative can keep for his or her own records, similar to how hospices are required by the hospice CoPs at § 418.52(a)(1) to provide the individual a copy of the notice of patient rights and responsibilities (85 FR 47091). The hospice CoPs at § 418.104(a)(2) state that the patient's record must include ''signed copies of the notice of patient rights in accordance with § 418.52.'' Likewise, since the addendum is part of the election statement as set forth in § 418.24(b)(6), then it is required to be part of the patient's record (if requested by the beneficiary or representative). The signed addendum is only acknowledgement of the beneficiary's (or representative's) receipt of the addendum (or its updates) and the payment requirement is considered met if there is a signed addendum (and any signed updates) in the requesting beneficiary's medical record with the hospice. We believe that a signed addendum indicates the hospice discussed the addendum and its contents with the beneficiary (or representative). Additionally, in the event that a beneficiary (or representative) does not request the addendum, we expect hospices to document, in some fashion, that an addendum has been discussed with the patient (or representative) at the time of election, similar to how other patient and family discussions are documented in the hospice's clinical record. It is necessary for the hospice to document that the addendum was discussed and whether or not it was requested, in order to prevent potential claims denials related to any absence of an addendum (or addendum updates) in the medical record.

Though we did not propose any changes to the election statement addendum content requirements at § 418.24(c), or the October 1, 2020 effective date, in the FY 2021 Hospice Wage Index and Payment Rate Update proposed rule, we solicited comments on the usefulness of the modified model election statement and addendum posted on the Hospice Center web page (85 FR 20949). In the FY 2021 Hospice Wage Index and Payment Rate Update final rule (85 FR 47093), we responded to comments received, and stated that, as finalized in the FY 2020 Hospice Wage Index and Payment Rate Update final rule, the hospice election statement addendum will remain a condition for payment that is met when there is a signed addendum (and its updates) in the beneficiary's hospice medical record.

Since its implementation on October 1, 2020, CMS has received additional inquiries from stakeholders asking for clarification on certain aspects of the addendum. We appreciate and understand the importance of provider input and involvement in ensuring that this document is effective in increasing coverage transparency for beneficiaries. Therefore, in the FY 2022 proposed rule (86 FR 19724) we provided clarification on, and proposed modifications to, certain signature and timing requirements and proposed corresponding clarifying regulations text changes.

Currently the regulations at § 418.24(c) require that if a beneficiary or his or her representative requests the addendum at the time of the initial hospice election (that is, at the time of admission to hospice), the hospice must provide this information, in writing, to the individual (or representative) within 5 days from the date of the election. In the FY 2022 hospice proposed rule, we noted that hospices have reported that beneficiaries or representatives sometimes do not request the addendum at the time of election, but rather within the 5 days after the effective date of the election (86 FR 19724). In these situations, the regulations require the hospice to provide the addendum within 3 days, as the beneficiary requested the addendum during the course of care. However, in accordance with § 418.54(b), the hospice IDG, in consultation with the individual's attending physician (if any), must complete the hospice comprehensive assessment no later than 5 calendar days after the election of hospice care. We stated that in some instances, this may mean that the hospice must furnish the addendum prior to completion of the comprehensive assessment. The comprehensive assessment includes all areas of hospice care related to the palliation and management of a beneficiary's terminal illness. This assessment is necessary because it provides an overview of the items, services and drugs that the patient is already utilizing as well as helps determine what the hospice may need to add in order to treat the patient throughout the dying process. If the addendum is completed prior to the comprehensive assessment, the hospice may not have a complete patient profile, which could potentially result in the hospice incorrectly anticipating the extent of covered and non-covered services and lead to an inaccurate election statement addendum. Hospice

[6] Hospice web page. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.*

providers are only able to discern what items, services, and drugs they will not cover once they have a beneficiary's comprehensive assessment. We proposed allowing the hospice to furnish the addendum within 5 days from the date of a beneficiary or representative request, if the request is within 5 days from the date of a hospice election. For example, if the patient elects hospice on December 1st and requests the addendum on December 3rd, the hospice would have until December 8th to furnish the addendum.

Additionally, we acknowledged that hospices have noted that there is not a timeframe in regulations regarding the patient signature on the addendum. Section 418.24(c)(9) requires the beneficiary's signature (or his/her representative's signature) as well as the date the document was signed. We noted in the FY 2021 Hospice Wage Index & Payment Rate Update final rule that because the beneficiary signature is an acknowledgement of receipt of the addendum, this means the beneficiary would sign the addendum when the hospice provides it, in writing, to the beneficiary or representative (85 FR 47092). Obtaining the required signatures on the election statement has been a longstanding regulatory requirement. Therefore, we stated that we expect that hospices already have processes and procedures in place to ensure that required signatures are obtained, either from the beneficiary, or from the representative in the event the beneficiary is unable to sign, and we anticipate that hospices would use the same procedures for obtaining signatures on the addendum. We did note that we understand that some beneficiaries or representatives may request an emailed addendum or request more time to review the addendum before signing, in which case the date that the hospice furnished the addendum to the beneficiary (or representative) may differ from the date that the beneficiary or representative signs the addendum. This means the hospice may furnish the addendum within the required timeframe; however, the signature date may be beyond the required timeframe. Therefore, we proposed to clarify in regulation that the ''date furnished'' must be within the required timeframe (that is, 3 or 5 days of the beneficiary or representative request, depending on when such request was made), rather than the signature date. At § 418.24(c)(10), we proposed that the hospice would include the ''date furnished'' in the patient's medical record and on the addendum itself.

In the FY 2021 Hospice Wage Index and Payment Rate Update final rule, we addressed a concern regarding a potential situation wherein the beneficiary or representative refuses to sign the addendum (85 FR 47088). We reiterated that the signature on the addendum is only acknowledgement of receipt and not a tacit indication of agreement with its contents, and that we expect the hospice to inform the beneficiary of the purpose of the addendum and rationale for the signature. However, we recognized that there might be rare instances in which the beneficiary (or representative) refuses to sign the addendum, and noted that we would consider whether this issue would require future rulemaking. In the proposed rule, we stated that we have subsequently received this question from stakeholders post implementation, and therefore, clarified that if a patient or representative refuses to sign the addendum, the hospice must document clearly in the medical record (and on the addendum itself) the reason the addendum is not signed in order to mitigate a claims denial for this condition for payment. We stated that in such a case, although the beneficiary has refused to sign the addendum, the ''date furnished'' must still be within the required timeframe (that is, within 3 or 5 days of the beneficiary or representative request, depending on when such request was made), and noted in the chart and on the addendum itself (86 FR 19725).

We also noted that stakeholders again requested that CMS clarify whether a non-hospice provider is required to sign the addendum in the event that the non-hospice provider requests the addendum rather than the beneficiary or representative. We reiterated that if only a non-hospice provider or Medicare contractor requests the addendum (and not the beneficiary or representative) we would not expect a signed copy in the patient's medical record. We stated that hospices can develop processes (including how to document such requests from non-hospice providers and Medicare contractors) to address circumstances in which the non-hospice provider or Medicare contractor requests the addendum, and the beneficiary or representative does not (86 FR 19725). As such, we proposed to clarify in regulation that if a non-hospice provider requests the addendum, rather than the beneficiary or representative, the non-hospice provider is not required to sign the addendum.

We also discussed that there may be instances in which the beneficiary or representative requests the addendum and the beneficiary dies, revokes, or is discharged prior to signing the addendum (86 FR 19725). While we stated in the FY 2020 Hospice Wage Index and Payment Rate Update final rule, that if the beneficiary requests the election statement addendum at the time of hospice election but dies within 5 days, the hospice would not be required to furnish the addendum as the requirement would be deemed as being met in this circumstance (84 FR 38521), this policy was not codified in regulation. Therefore, we proposed conforming regulations text changes at § 418.24(c) to reflect this policy. Furthermore, we proposed to clarify at § 418.24(d)(4) that if the patient dies, revokes election, or is discharged within the required timeframe (3 or 5 days after a request, depending upon when such request was made), but the hospice has not yet furnished the addendum, the hospice is not required to furnish the addendum. Similarly, we proposed to clarify at § 418.24(d)(5) that in the event that a beneficiary requests the addendum and the hospice furnishes the addendum within 3 or 5 days (depending upon when the request for the addendum was made), but the beneficiary dies, revokes, or is discharged prior to signing the addendum, a signature from the individual (or representative) is no longer required. We stated that we would continue to expect that the hospice would note the ''date furnished'' in the patient's medical record and on the addendum, if the hospice has already completed the addendum, as well as an explanation in the patient's medical record noting that the patient died, revoked, or was discharged prior to signing the addendum (86 FR 19725).

Finally, we proposed conforming regulations text changes at § 418.24(c) in alignment with subregulatory guidance indicating that hospices have ''3 days,'' rather than ''72 hours'' to meet the requirement when a patient requests the addendum during the course of a hospice election. We proposed that hospices must furnish the addendum no later than 3 calendar days after a beneficiary's (or representative's) request during the course of a hospice election. This means that hospice providers must furnish the addendum to the beneficiary or representative on or before the third day after the date of the request. For example, if a beneficiary (or representative) requests the addendum on February 22nd, then the hospice will have until February 25th to furnish the addendum, regardless of what time the addendum was requested on February

22nd. The intent of this clarification is to better align with the requirement for furnishing an election statement addendum when the addendum is requested within 5 days of the date of election, which also uses ''days'' rather than ''hours''.

Thirty-one unique stakeholders submitted their comments on the proposed clarifications to the election statement addendum. A few commenters requested additional clarification on certain topics and offered recommendations for the election statement addendum. These comments along with our responses are summarized below.

Comment: The majority of commenters supported the clarifications and proposed regulation text changes regarding the election statement addendum. Commenters thanked CMS for these regulatory changes, stating that these clarifications will facilitate administration of the addendum and reduce hospice burden.

Response: We thank commenters for their feedback.

Comment: Some commenters recommended that the timeframe to furnish the addendum to the beneficiary (or representative) when requested after the first 5 days of a hospice election be changed from 3 days to 5 days. Other commenters recommended that CMS change the requirement from 3 calendar days to 3 business days. One commenter requested clarification that the day of request is considered day zero. Another commenter mentioned that providing the addendum within 3 days is burdensome to beneficiaries (or representatives), because they felt pressured to meet with hospice staff to provide their signature for the requested addendum.

Response: We did not propose to change the timeline for furnishing the addendum when a beneficiary requests the addendum during the course of a hospice election (that is, after the first five days of a hospice election date), and we continue to believe that 3 days is an adequate amount of time for the hospice to furnish the addendum. As we stated in the FY 2020 hospice final rule, because the hospice has already completed the comprehensive assessment and has begun providing care, we believe that this represents a sufficient timeframe for reviewing the patient record and completing the addendum if this information is requested during the course of hospice care (84 FR 38511).

Additionally, as the plan of care should identify the conditions or symptoms that the hospice determines to be ''unrelated,'' this information should be readily accessible to the hospice in order to allow for the timely completion of the addendum. Hospices should update the addendum to include such conditions, items, services, and drugs they determine to be unrelated throughout the course of a hospice election. Hospices are able to create their own process when it comes to updating and providing the requested addendum to the beneficiary (or representative). Furthermore, we believe 3 calendar days, rather than 3 business days continues to be appropriate, as hospice care is provided around the clock rather than only during business days and hours.

In the proposed rule, we provided an example acknowledging the day of the request as day zero. We stated that when the request is within 5 days from the date of a hospice election, and the patient elects hospice on December 1st and requests the addendum on December 3rd, the hospice would have until December 8th to furnish the addendum (86 FR 19724), making December 1st as day zero in this example. Moreover, because we proposed to change the timeframe requirements to correspond with the ''date furnished'' rather than the ''signature date,'' we disagree that this timeframe would be burdensome to beneficiaries. We noted in the FY 2021 Hospice Wage Index & Payment Rate Update final rule that because the beneficiary signature is an acknowledgement of receipt of the addendum, this means the beneficiary would sign the addendum when the hospice provides it, in writing, to the beneficiary or representative (85 FR 47092). Obtaining the required signatures on the election statement has been a longstanding regulatory requirement (84 FR 38484); however, we did acknowledge in the proposed rule that there may be time constraints and/or circumstances that would prevent a beneficiary from signing and returning the addendum to the hospice by a specified deadline. We proposed to require that the ''date furnished'' be within the required timeframe, rather than the signature date, to mitigate any undue strain on the beneficiary or representative in returning the addendum to the hospice by a specified date.

Comment: Some commenters expressed concern that the request from a non-hospice provider for the election statement addendum does not require a signature. Commenters stated that hospices would have no proof that the addendum was provided to the non-hospice provider without the provider's signature.

Response: If a non-hospice provider requests the addendum, the hospice must furnish the addendum, however, the non-hospice provider is not required to sign the addendum. We remind commenters that the intent of the addendum is to ensure that hospice beneficiaries and their representatives are fully informed of any items or services for which they must assume financial responsibility. Consequently, if only a non-hospice provider or Medicare contractor request the addendum (and not the beneficiary or representative) CMS would not expect a signed copy in the patient's medical record. Hospices can develop processes (including how to document such requests from non-hospice providers and Medicare contractors) to address circumstances in which the non-hospice provider or Medicare contractor requests the addendum, and the beneficiary or representative does not, as a means of demonstrating that the addendum was furnished to a non-hospice provider and/or Medicare contractor upon request.

Comment: A commenter asked CMS to define whether or not a mailed copy of the form would be acceptable. The commenter stated that they believe their patients and their representatives would welcome this option; however, it is unclear whether mailing the form is acceptable for CMS.

Response: There is nothing precluding hospices from furnishing an addendum through mail. We expect that hospices would take steps in working with patients and their representatives to better understand which methods (that is, in person, mail, etc.) of delivery would work best in furnishing the addendum. Some beneficiaries or representatives may have time constraints that prevent them from signing and returning the addendum by a certain deadline, in which case, the date that the hospice furnishes the addendum to the beneficiary may differ from the date that the beneficiary (or representative) signs the addendum. Hospices would need to make sure the ''date furnished' on the addendum is within the required timeframe (3 or 5 days, depending upon when the request was made). Furthermore, we expect that hospices will have processes in place when they are obtaining a signed addendum from a beneficiary or representative.

Comment: Many commenters requested making the proposed clarifications to the hospice election statement addendum retroactive to the implementation date of October 1, 2020. One commenter requested delaying the effective date of the proposed

clarification for the hospice election statement addendum to provide time for software updates in addition to reporting and system alerts.

Response: We do not believe that making these clarifications retroactive or delaying the effective date is necessary. To date we have not received reports of claims denials resulting from the implementation of the election statement addendum and the current regulations at § 418.24. Furthermore, many of these clarifying regulations text changes have been previously addressed in sub-regulatory guidance. As such, the implementation of these clarifications on October 1, 2021 would not cause a burden for software updates.

Comment: Many commenters encouraged CMS to update the model hospice election statement addendum on the CMS hospice center web page to illustrate these clarifications.

Response: We will post an updated model election statement addendum on the Hospice web page,[7] along with the publication of this FY 2022 Hospice Wage Index and Payment Rate Update final rule. This is an illustrative example for hospices to modify and develop their own forms that meet the content requirements at § 418.24.

Comment: Some commenters stated that it is redundant to require the hospice to note on the addendum and in the medical record the reason that a beneficiary did not provide their signature.

Response: We recognize the commenters' concerns and agree that it is appropriate for the hospice to document only on the addendum itself the reason that an addendum is un-signed. This could include not only a beneficiary refusing to sign, but also death, discharge, or revocation prior to the hospice obtaining the signature. However, while a hospice can choose to document the reason for an unsigned addendum in the medical record, as well as on the addendum, it is not required.

Comment: Many commenters offered suggestions regarding additional aspects of the election statement addendum for which we did not propose clarifying changes. Some commenters recommended that CMS align the late penalty for the addendum with the penalty for late submission of the NOE. Other commenters stated that denying the whole hospice claim when the addendum is furnished late is excessive. A commenter stated that as currently structured, the penalty is a negative incentive to furnish the addendum in a timely manner if a hospice misses the initial required timeframe. Some commenters mentioned there was confusion regarding billing when an addendum is furnished late. Other commenters recommended using a code to indicate billed but not covered hospice days when the addendum is furnished late. A few commenters stated they believe the addendum and the ABN have the potential to decrease transparency and increase confusion for hospice patients, whereas, other commenters recommended expanding the usage of the addendum, which included combining the ABN and addendum, and to include drugs or services which the hospice has determined to be medically unreasonable or no longer necessary. One commenter recommended that CMS explore ways to educate hospice providers about how they can inform their beneficiaries (or representative) when items, services, or drugs are considered related, but non-covered due to reasons such as not reasonable or necessary for the palliation and management of the terminal illness and related conditions. Moreover, a commenter recommended developing an exceptions process for when hospice providers are unable to provide an addendum because of 'exceptional circumstances' that are beyond the control of the hospice. Lastly, one commenter suggested that since an electronically sent addendum could be tracked, a signature should not be required.

Response: While these comments are out of scope of the proposed rule, we appreciate and welcome all feedback related to the late penalty; ABN and expansion of the addendum; signatures; exceptional circumstances; and educating hospice providers. While we did not propose any of these recommendations we could consider them for future rulemaking. We understand the possibility of conflating the differences between the ABN and the hospice election statement addendum. The ABN transfers potential financial liability to the Medicare beneficiary in certain instances, whereas the addendum (upon request) informs terminally ill beneficiaries (or their representative) only of items, services, or drugs the hospice will not be providing because the hospice has determined them to be unrelated to the terminal illness and related conditions. We refer readers to FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38512) to learn more about the usage of the ABN. The hospice CoPs at § 418.56(b) require hospices to educate each patient and their primary caregivers(s) on services identified on the plan of care and document the patient's (or representative's) level of understanding involvement and agreement with the plan of care. We expect that hospices would use the same methods when educating patients (or representatives) about the addendum and non-covered items, services and drugs, which the hospice has determined are not reasonable or necessary for the palliation and management of the terminal illness and related conditions.

The hospice CoPs at § 418.52(a)(1) require that in advance of receiving care, patients are informed about their rights, and hospices must provide the patient (or representative) with verbal and written notice of the patient's rights and responsibilities in a language and manner the patient understands. Likewise, the hospice CoPs at § 418.52(a)(3) requires that hospices obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities. So, it is not unreasonable to require that the electronically sent addendum also be signed to ensure that the patient is aware of the important information about hospice non-covered items, services, and drugs. We do not have a policy for 'exceptional circumstances' (that is floods, hurricanes, etc.) but we will consider addressing this policy in future rulemaking.

Final Decision: We are finalizing the clarifications and addendum regulation text changes at § 418.24(c) as proposed, with the exception of requiring the reason that the addendum is not signed to be documented in the patient's medical record. This explanation must be clearly noted on the addendum itself, but is not required to be documented in both places. Based on comments, we are amending the regulation text at § 418.24 to state that if the beneficiary dies, revokes election, is discharged prior to signing the addendum, or refuses to sign the addendum, the addendum would not be required to be signed in order for the hospice to receive payment. The hospice must note (on the addendum itself) the reason the addendum was not signed and the addendum would become part of the patient's medical record. These changes will be effective on October 1, 2021.

[7] Hospice web page: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.*

E. Hospice Waivers Made Permanent Conditions of Participation

1. Background

In order to support provider and supplier communities due to the COVID–19 PHE, CMS has issued an unprecedented number of regulatory waivers under our statutory authority set forth at section 1135 of the Act. Under section 1135 of the Act, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the programs in the emergency area and time periods, and that providers who furnish such services in good faith, but who are unable to comply with one or more requirements as described under section 1135(b) of the Act, can be reimbursed and exempted from sanctions for violations of waived provisions (absent any determination of fraud or abuse). The intent of these waivers was to expand healthcare system capacity while continuing to maintain public and patient safety, and to hold harmless providers and suppliers unable to comply with existing regulations after a good faith effort.

While some of these waivers simply delay certain administrative deadlines, others directly affect the provision of patient care. The utilization and application of these waivers pushed us to consider whether permanent changes would be beneficial to patients, providers, and professionals. We identified selected waivers as appropriate candidates for formal regulatory changes. Those changes and their respective histories and background information are discussed in the rule. We are also finalizing regulatory changes that are not directly related to PHE waivers that will clarify or align some policies that have been raised as concerns by stakeholders.

We are finalizing the following revisions to the hospice CoPs.

2. Hospice Aide Training and Evaluation—Using Pseudo-Patients

Hospice aides deliver a significant portion of direct care. Aides are usually trained by an employer, such as a hospice, HHA or nursing home and may already be certified as an aide prior to being hired. The competency of new aides must be evaluated by the hospice to ensure appropriate care can be provided by the aide. Aide competency evaluations should be conducted in a way that identifies and meets training needs of the aide as well as the patient's needs. These evaluations are a critical part of providing safe, quality care.

The current hospice aide competency standard regulations at § 418.76(c)(1) requires the aide to be evaluated by observing an aide's performance of the task with a patient. We are finalizing similar changes to hospice aide competency standards to those already made with respect to HHAs (see § 484.80(c)) in our hospice regulations at § 418.76(c)(1)). Additionally, we are finalizing definitions for both ''pseudo-patient'' and ''simulation'' at § 418.3. Therefore, we are finalizing changes to permit skill competencies to be assessed by observing an aide performing the skill with either a patient or a pseudo-patient as part of a simulation. The final definitions are as follows:

- ''Pseudo-patient'' means a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the hospice aide trainee, and must demonstrate the general characteristics of the primary patient population served by the hospice in key areas such as age, frailty, functional status, cognitive status and care goals.
- ''Simulation'' means a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

These changes will allow hospices to utilize pseudo-patients, such as a person trained to participate in a role-play situation or a computer-based mannequin device, instead of actual patients, in the competency testing of hospice aides for those tasks that must be observed being performed on a patient. This could increase the speed of performing competency testing and would allow new aides to begin serving patients more quickly while still protecting patient health and safety.

3. Hospice Aide Training and Evaluation—Targeting Correction of Deficiencies

We are also amending the requirement at § 418.76(h)(1)(iii) to specify that if an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete, a competency evaluation of the deficient skill and all related skill(s) in accordance with § 418.76(c). This change will permit the hospice to focus on the hospice aides' specific deficient and related skill(s) instead of completing another full competency evaluation. We believe when a deficient area(s) in the aide's care is assessed by the RN, there may be additional related competencies that may also lead to additional deficient practice areas and thus would require that those skills be included in the targeted competency evaluation.

We received a total of 32 comments pertaining to the proposed revision to the CoPs. Commenters included individuals, hospice agencies, state hospice associations, national provider organizations, and patient advocacy groups. The response to those comments follows:

Comment: Commenters were overwhelmingly supportive of the provisions to permit the use of pseudo-patients and simulation when conducting hospice aide competency training and for retraining of deficient skills. Several commenters indicated that the changes will facilitate a more time-efficient process in the evaluation of aide skills. Another commenter stated the changes improve the efficiency of onboarding new staff in a safe and effective manner.

Response: We appreciate these comments and agree that the utilization of pseudo-patients and simulation will facilitate more timely completion of training requirements for newly hired hospice aides as well as allowing hospices to target specific competency training for hospice aides noted to have deficient skill(s) on the supervisory visit. We believe that this will benefit the hospice and the patient by allowing new aide trainees and aides requiring remedial training and competency testing to begin serving patients more quickly while protecting patient health and safety.

Comment: Several commenters stated that the use of pseudo-patients and simulation techniques are common in healthcare and a standard of practice in many formal nursing assistant programs. These commenters also state that hospices can adequately assess an aide's skills through these means during competency training. Another commenter indicated that the use of pseudo-patients and simulation will support patient privacy.

Response: We appreciate the commenters highlighting the use of pseudo-patients and simulation techniques in other healthcare setting and agree that the use of these techniques is standard of practice in many formal nursing assistant programs. We believe patient privacy is a fundamental right for those persons

receiving hospice care. We agree that permitting competency testing of hospice aides utilizing a pseudo-patient will support patient privacy while also assuring a competently trained hospice aide workforce that provide high quality patient care.

Comment: While the majority of commenters supported the proposed changes; one commenter did not support the use of the pseudo-patient or targeted competency testing. The commenter suggested that more research and data are required on the use of pseudo-patients and changes to competency requirements prior to making a policy decision. The commenter also stated that data and research should support that using a non-patient in training is safe when aides subsequently provide care. Additionally, the commenter raised concerns regarding instances when multiple areas of deficient practice are noted and if a full competency would be done these instances.

Response: We appreciate the commenter's concern and the request for additional research in this area. We believe, and other commenters noted, that the use of pseudo-patients and simulation is an accepted standard of practice for training in healthcare, including nurse aide training programs. These same requirements were implemented for home health aide supervision in 2019 (see 84 FR 51732 and the associated regulations at § 484.80(c)(1)), without any reported adverse impacts noted to-date in CMS survey data or complaints being reported to CMS. Both the use of the pseudo-patient and targeted aide training align requirements between these two providers, home health and hospice, affording the opportunity for efficiency in implementation for many agencies that are Medicare certified to provide both services.

When deficient aide skills are noted during a supervisory visit, the RN determines the deficient skills and all related skills that may be impacted. The supervising RN then determines the scope of the competency testing required, which may include a full competency testing of all skills if warranted, such as when multiple areas of deficient practice are noted.

Comment: One commenter recommended CMS broaden its view of nurses to include licensed practical nurses (LPNs) for conducting aide supervisory visits. The commenter indicated that this change would provide greater staffing flexibility for hospices given workforce shortages among essential workers.

Response: We appreciate the recommendation to permit greater flexibility for hospices in regards to staffing of essential workers. However, we have previously addressed this matter in prior rulemaking (see Medicare and Medicaid Programs: Hospice Conditions of Participation; final rule; 73 FR 32131 issued June 5, 2008) and believe the rationale for requiring a RN for conducting supervisory visits continues to be warranted. Registered nurses, through their education, training, and role in provision of hospice care, are best positioned to assess the adequacy of the aide services in relationship to the needs of the patient and family to a greater degree than LPNs, or licensed vocational nurses (LVNs). Ideally, the supervising RN is both responsible for supervision of the aide services as well as being primarily responsible for the patient's nursing care. This allows the RN to develop a complete picture of the patient and family and of the aide's services.

Comment: Many commenters stated that focusing the competency training on specific deficient skills provided greater efficiency for hospices. One commenter indicated that comprehensive competency testing can take up to a full 8-hour day and a targeted approach will save time related to this requirement. Another commenter stated that completing a full competency test takes the focus away from the identified deficiency and is not effective. A third commenter stated that topic-specific evaluations will significantly reduce time and allow hospices to concentrate on the specific deficient skills with additional practice and training.

Response: We appreciate the support for this comment and agree that a targeted approach is both more efficient and will permit greater focus on remediating the deficient skills.

Comment: Many commenters requested clarification related to the use of technology under the Medicare hospice benefit during the PHE. These commenters requested that CMS further clarify that technology-based visits are permissible outside of a PHE under the same circumstances and conditions as under a PHE, provided applicable HIPAA requirements are met, and requested that CMS establish modifiers that can be used on claims to designate such visits.

Response: While comments on this topic are out of scope for this rulemaking, we do believe the subject is important to address, given the number of comments on this topic. On April 6, 2020, we published an interim final rule ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 19230). This rule provided individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of COVID–19. The rule implemented temporary changes to the hospice payment requirements to provide broad flexibilities to furnish services using telecommunications technology in order to avoid exposure risks to health care providers, patients, and the community during the PHE. These changes will expire at the end of the COVID–19 PHE. The use of telehealth for conducting the required hospice face-to-face (F2F) encounter is statutorily limited to the PHE for COVID–19 in accordance with section 1814(a)(1)(7)(D)(i) of the Act, as amended by section 3706 of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136).

The CoPs are not relevant to payment questions regarding the use of technology, such as telehealth, in the provision of hospice services. The standard of practice for hospice is that care and services are provided on an in-person basis based on needs identified in the comprehensive assessment and services ordered by the IDG and outlined in the plan of care. While nothing in the COPs prevent hospices from augmenting in-person visits with technological means, such as telehealth, these are not intended to change the standard of practice or replace in-person visits. Additionally, for the duration of the PHE, we expect that it would be up to the clinical judgment of hospice as to whether such technology can meet the patient's/caregiver's/family's needs and the use of technology should be included on the plan of care for the patient and family.

We will continue to evaluate the impact of the COVID–19 PHE. At this point, we are still assessing the impact of all waivers and flexibilities on beneficiaries and the delivery of healthcare services under the PHE. While the impact of some waiver and flexibilities may be more apparent at this time, such as the waivers related to hospice aide supervision, flexibilities associated with other aspects of care are more complex requiring additional time for a complete understanding of their impact. We will continue to evaluate the flexibilities to determine if additional changes are warranted in the future.

Final Rule Action: We are finalizing as proposed at § 418.76(c)(1) our policy that hospices may conduct competency testing by observing an aide's

performance of the task with a patient or pseudo-patient. Additionally, we are finalizing as proposed at § 418.3 the definitions of ''pseudo-patient'' and ''simulation''.

We are also finalizing as proposed the requirement at § 418.76(h)(1)(iii) to specify that if an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete, a competency evaluation of the deficient skill and all related skill(s) in accordance with § 418.76(c).

F. Updates to the Hospice Quality Reporting Program

1. Background and Statutory Authority

The Hospice Quality Reporting Program (HQRP) specifies reporting requirements for both the Hospice Item Set (HIS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey. Section 1814(i)(5) of the Act requires the Secretary to establish and maintain a quality reporting program for hospices. Section 1814(i)(5)(A)(i) of the Act was amended by section 407(b) of Division CC, Title IV of the CAA 2021 (Pub. L. 116–260) to change the payment reduction for failing to meet hospice quality reporting requirements from 2 to 4 percentage points. This policy will apply beginning with FY 2024 annual payment update (APU). Specifically, the Act requires that, beginning with FY 2014 through FY 2023, the Secretary shall reduce the market basket update by 2 percentage points and beginning with the FY 2024 APU and for each subsequent year, the Secretary shall reduce the market basket update by 4 percentage points for any hospice that does not comply with the quality data submission requirements for that FY. We noted this revised statutory requirement in our proposed rule (86 FR 19726) and are codifying the revision at § 418.306(b)(2).

In addition, section 407(a)(2) of the CAA 2021 removes the prohibition on public disclosure of hospice surveys performed be a national accreditation agency in section 1865(b) of the Act, thus allowing the Secretary to disclose such accreditation surveys. In addition, section 407(a)(1) of the CAA 2021 adds new requirements in a newly added section 1822(a)(2) to require each state and local survey agency, and each national accreditation body with an approved hospice accreditation program, to submit information regarding any survey or certification made with respect to a hospice program. Such information shall include any inspection report made by such survey agency or body with respect to such survey or certification, any enforcement actions taken as a result of such survey or certification, and any other information determined appropriate by the Secretary. This information will be published publicly on our website, such as Care Compare, in a manner that is easily accessible, readily understandable, and searchable no later than October 1, 2022. In addition, national accreditation bodies with approved hospice accreditation programs are required to use the same survey form used by state and local survey agencies, which is currently the Form CMS–2567, on or after October 1, 2021.

Depending on the amount of the annual update for a particular year, a reduction of 2 percentage points through FY 2023 or 4 percentage points beginning in FY 2024 could result in the annual market basket update being less than zero percent for a FY and may result in payment rates that are less than payment rates for the preceding FY. Any reduction based on failure to comply with the reporting requirements, as required by section 1814(i)(5)(B) of the Act, would apply only for the specified year. Any such reduction would not be cumulative nor be taken into account in computing the payment amount for subsequent FYs. We are revising the regulations text at § 418.306(b)(2) under a ''good cause'' waiver of proposed rulemaking as this change was noted in the proposed rule and is a statutory requirement of the CAA of 2021. Under the Administrative Procedure Act (APA) (5 U.S.C. 553), the agency is not required to conduct notice and comment rulemaking for a change that is statutory. Section V. of this final rule further details this waiver of proposed rulemaking. Thus, 42 CFR 418.306(b)(2) has been revised to follow the CAA of 2021 updates for the survey agencies.

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. The data must be submitted in a form, manner, and at a time specified by the Secretary. Any measures selected by the Secretary must have been endorsed by the consensus-based entity which holds a performance measurement contract with the Secretary under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). However, section 1814(i)(5)(D)(ii) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the consensus-based entity, the Secretary may specify measures that are not endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization identified by the Secretary. Section 1814(i)(5)(D)(iii) of the Act requires that the Secretary publish selected measures applicable with respect to FY 2014 no later than October 1, 2012.

In the FY 2014 Hospice Wage Index and Payment Rate Update final rule (78 FR 48234), and in compliance with section 1814(i)(5)(C) of the Act, we finalized the specific collection of data items that support the seven NQF-endorsed hospice measures described in Table 6. In addition, we finalized the Hospice Visits When Death is Imminent measure pair (HVWDII, Measure 1 and Measure 2) in the FY 2017 Hospice Wage Index and Payment Rate Update final rule, effective April 1, 2017. We refer the public to the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52144) for a detailed discussion.

The CAHPS Hospice Survey is a component of the CMS HQRP, which is used to collect data on the experiences of hospice patients and their family caregivers listed in their hospice records. Readers who want more information about the development of the survey, originally called the Hospice Experience of Care Survey, may refer to 79 FR 50452 and 78 FR 48261. National implementation of the CAHPS Hospice Survey commenced January 1, 2015, as stated in the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452).

The CAHPS Hospice Survey measures received NQF endorsement on October 26, 2016 and was re-endorsed November 20, 2020 (NQF #2651). NQF endorsed six composite measures and two overall measures from the CAHPS Hospice Survey. Along with nine HIS-based quality measures, the CAHPS Hospice Survey measures are publicly reported on a designated CMS website that is currently Care Compare. Beginning no earlier than May 2022, the Hospice Visits in Last Days of Life measure and the Hospice Care Index will also be publicly reported on the CMS website. Table 6 lists all quality measures planned for FY 2022 for HQRP.

TABLE 6: Quality Measures planned for FY 2022 for the Hospice Quality Reporting Program

Hospice Item Set	
NQF#	**Short name**
3235	Hospice and Palliative Care Composite Process Measure—HIS-Comprehensive Assessment Measure at Admission includes: 1. Patients Treated with an Opioid who are Given a Bowel Regimen (NQF #1617) 2. Pain Screening (NQF#1634) 3. Pain Assessment (NQF #1637) 4. Dyspnea Treatment (NQF #1638) 5. Dyspnea Screening (NQF# 1639) 6. Treatment Preferences (NQF #1641) 7. Beliefs/Values Addressed (if desired by the patient) (NQF# 1647)
Claims-based Measures	
Not applicable	Hospice Visits in Last Days of Life (HVLDL)
Not applicable	Hospice Care Index (HCI) 1. Continuous Home Care (CHC) or General Inpatient (GIP) Provided 2. Gaps in Skilled Nursing Visits 3. Early Live Discharges 4. Late Live Discharges 5. Burdensome Transitions (Type 1) – Live Discharges from Hospice Followed by Hospitalization and Subsequent Hospice Readmission 6. Burdensome Transitions (Type 2) – Live Discharges from Hospice Followed by Hospitalization with the Patient Dying in the Hospital 7. Per-beneficiary Medicare Spending 8. Skilled Nursing Care Minutes per Routine Home Care (RHC) Day 9. Skilled Nursing Minutes on Weekends 10. Visits Near Death
CAHPS Hospice Survey	
2651	CAHPS Hospice Survey – single measure • Communication with Family • Getting timely help • Treating patient with respect • Emotional and spiritual support • Help for pain and symptoms • Training family to care for the patient • Rating of this hospice • Willing to recommend this hospice

The Hospice and Palliative Care Composite Process Measure—HIS-Comprehensive Assessment at Admission measure (hereafter referred to as ''the HIS Comprehensive Assessment Measure'') underwent an off-cycle review by the NQF Palliative and End-of-Life Standing Committee and successfully received NQF endorsement in July 2017 (NQF 3235). The HIS Comprehensive Assessment Measure captures whether multiple key care processes were delivered upon patients' admissions to hospice in one measure as described in the Table 6. NQF 3235 does not require NQF's endorsements of the previous components to remain valid. Thus, if the components included in NQF 3235 do not individually maintain endorsement, the endorsement status of NQF 3235, as a single measure, will not change.

In the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47142), we finalized the policy for retention of HQRP measures adopted for previous payment determinations and seven factors for measure removal. In that same final rule, we discussed that we will issue public notice, through rulemaking, of measures under consideration for removal, suspension, or replacement. However, if there is reason to believe continued collection of a measure raises potential safety concerns, we will take immediate action to remove the measure from the HQRP and will not wait for the annual

rulemaking cycle. Such measures will be promptly removed and we will immediately notify hospices and the public of our decision through the usual HQRP communication channels, including but not limited to listening sessions, email notification, Open Door Forums, HQRP Forums, and Web postings. In such instances, the removal of a measure will be formally announced in the next annual rulemaking cycle.

In the FY 2019 Hospice Wage Index and Rate Update final rule (83 FR 38622), we also adopted an eighth factor for removal of a measure. This factor aims to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. These costs are multifaceted and include the burden associated with complying with the program. The finalized reasons for removing quality measures are:

1. Measure performance among hospices is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made;
2. Performance or improvement on a measure does not result in better patient outcomes;
3. A measure does not align with current clinical guidelines or practice;
4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available;
5. A measure that is more proximal in time to desired patient outcomes for the particular topic is available;
6. A measure that is more strongly associated with desired patient outcomes for the particular topic is available;
7. Collection or public reporting of a measure leads to negative unintended consequences; or
8. The costs associated with a measure outweighs the benefit of its continued use in the program.

On August 31, 2020, we added correcting language to the FY 2016 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements; Correcting Amendment (85 FR 53679) hereafter referred to as the FY 2021 HQRP Correcting Amendment. In this final rule, we made correcting amendments to 42 CFR 418.312 to correct technical errors identified in the FY 2016 Hospice Wage Index and Payment Rate Update final rule. Specifically, the FY 2021 HQRP Correcting Amendment (85 FR 53679) adds paragraph (i) to § 418.312 to reflect our exemptions and extensions requirements, which were referenced in the preamble but inadvertently omitted from the regulations text. Thus, these exemptions or extensions can occur when a hospice encounters certain extraordinary circumstances.

As stated in the FY 2019 Hospice Wage Index and Rate Update final rule (83 FR 38622), we launched the Meaningful Measures initiative (which identifies high priority areas for quality measurement and improvement) to improve outcomes for patients, their families, and providers while also reducing burden on clinicians and providers. More information about the Meaningful Measures initiative can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

In the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38484), we discussed our interest in developing quality measures using claims data, to expand data sources for quality measure development. While we acknowledged in that rule the limitations with using claims data as a source for measure development, there are several advantages to using claims data as part of a robust HQRP as discussed previously in the FY 2020 rule. We also discussed developing the Hospice Outcomes & Patient Evaluation (HOPE), a new patient assessment instrument that is planned to replace the HIS. See an update on HOPE development in section III.F.6, ''Update regarding the Hospice Outcomes & Patient Evaluation (HOPE) development''.

We also discussed our interest in outcome quality measure development. Unlike process measures, outcome measures capture the results of care as experienced by patients, which can include aspects of a patient's health status and their experiences in the health system. The portfolio of quality measures in the HQRP will include outcome measures that reflect the results of care.

We received comments from various stakeholders on the proposals and updates including a consumer advocacy group, health care providers, hospice provider organizations, hospice trade groups, including those focused on rural providers, consultants, EHR vendors, and MedPAC.

Comment: We received a comment that we are making many updates in this rule and the resources for them are significant, especially during the COVID–19 Public Health Emergency (PHE). They ask us to consider a more gradual transition to new quality initiatives, staggered and prioritized.

Response: We are mindful of the burden related to our updates. We purposely made no updates or proposals in the FY 2021 final rule during the COVID–19 PHE. For FY 2022, two of the four measures we proposed to add were claims-based measures which do not increase burden to providers. We also proposed to remove multiple measures thus leading to a net decrease of total measures. Under our proposal, the HQRP will go from 10 measures down to 4 measures with two of these measures being claims-based measures, and the two already publicly reported measures of the CAHPS Hospice Survey and NQF #3235, the HIS-Comprehensive Assessment Measure. The public reporting has been thoughtfully considered as discussed in this rule so that providers can access their data earlier and prepare for public reporting in FY 2022, no sooner than May 2022. We also consider this work in coordination with planned future HOPE implementation and ensuring that the HQRP now covers the entire hospice stay with these 4 measures rather than just admission and discharge.

2. Removal of the Seven ''Hospice Item Set Process Measures'' From HQRP Beginning FY 2022

In the FY 2014 Hospice Wage Index and Payment Rate Update final rule (78 FR 48234), and in compliance with section 1814(i)(5)(C) of the Act, we finalized the specific collection of standardized data items, known as the HIS, that support the following NQF-endorsed measures:

- NQF #1617 Patients Treated with an Opioid who are Given a Bowel Regimen
- NQF #1634 Pain Screening
- NQF #1637 Pain Assessment
- NQF #1638 Dyspnea Treatment
- NQF #1639 Dyspnea Screening
- NQF #1641 Treatment Preferences
- NQF #1647 Beliefs/Values Addressed (if desired by the patient)

These measures were adopted to increase public awareness of key components of hospice care, such as pain and symptom management and non-clinical care needs. Consistent with our policy for measure retention and removal, finalized in the FY 2016 Hospice Wage Index and Rate Update final rule (80 FR 47142), we reviewed these measures against the factors for removal. Our analysis found that they meet factor 4: ''a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.'' We determined that the HIS Comprehensive

Assessment Measure, discussed in detail in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52144), is a more broadly applicable measure and continues to provide, in a single measure, meaningful differences between hospices regarding overall quality in addressing the physical, psychosocial, and spiritual factors of hospice care upon admission.

The HIS Comprehensive Assessment Measure's ''all or none'' criterion requires hospices to perform all seven care processes in order to receive credit. In this way, it is different from an average-based composite measure and sets a higher bar for performance. This single measure differentiates hospices and holds them accountable for completing all seven process measures to ensure core services of the hospice comprehensive assessment are completed for all hospice patients. Therefore, the HIS Comprehensive Assessment Measure continues to encourage hospices to improve and maintain high performance in all seven processes simultaneously, rather than rely on its component measures to demonstrate quality hospice care in a way that may be hard to interpret for consumers. The individual measures show performance for only one process and do not demonstrate whether the hospice provides high-quality care overall, as an organization. For example, a hospice may perform extremely well assessing treatment preferences, but poorly on addressing pain. High-quality hospice care not only manages pain and symptoms of the terminal illness, but assesses non-clinical needs of the patient and family caregivers, which is a hallmark of patient-centered care. Since the HIS Comprehensive Assessment Measure captures all seven processes collectively, we believe that public display of the individual component measures is not necessary.

The interdisciplinary, holistic scope of the HIS Comprehensive Assessment Measure aligns with the public's expectations for hospice care. In addition, the measure supports alignment across our programs and with other public and private initiatives. The seven individual components address care processes around hospice admission that are clinically recommended or required in the hospice CoPs. The Medicare Hospice CoPs require that hospice comprehensive assessments identify patients' physical, psychosocial, emotional, and spiritual needs and address them to promote the hospice patient's comfort throughout the end-of-life process. Furthermore, the person-centered, family, and caregiver perspective align with the domains identified by the CoPs and the National Consensus Project [8] as patients and their family caregivers also place value on physical symptom management and spiritual/psychosocial care as important factors at the end-of-life. The HIS Comprehensive Assessment Measure is a composite measure that serves to ensure all hospice patients receive a comprehensive assessment for both physical and psychosocial needs at admission.

In addition, MedPAC's Report to Congress: Medicare Payment Policy [9] in recent years noted that the HIS Comprehensive Assessment Measure differentiates the hospice's overall ability to address care processes better than the seven individual HIS process measures. In this way, it provides consumers viewing data on Care Compare with a streamlined way to assess the extent to which a hospice follows care processes. In this final rule, we are not making any revisions to the HIS Comprehensive Assessment Measure because the single measure continues to show sufficient variability and therefore provides value to patients, their families, and providers.

Because the HIS Comprehensive Assessment Measure is a more broadly applicable measure, we are finalizing our proposal to remove the seven individual HIS process measures from the HQRP, no longer publicly reporting them as individual measures on Care Compare beginning with FY 2022. In addition, we proposed and finalize in this rule to remove the ''7 measures that make up the HIS Comprehensive Assessment Measure'' section of Care Compare, which displays the seven HIS measures. We proposed and are finalizing these changes to remove the seven HIS process measures as individual measures from HQRP no earlier than May 2022.

Although we would remove the seven individual HIS process measures, it does not change the requirement to submit the HIS admission assessment. Since the HIS Comprehensive Assessment Measure is a composite of the seven HIS process measures, the burden and requirement to report the HIS data remain unchanged in the time, manner, and form finalized in the FY 2017 Hospice Wage Index and Rate Update final rule (81 FR 52144). Hospices which do not report HIS data used for the HIS Comprehensive Assessment Measure will not meet the requirements for compliance with the HQRP.

We solicited public comment on the proposal to remove the seven HIS process quality measures as individual measures from the HQRP no earlier than May 2022, and to continue including the seven HIS process measures in the confidential quality measure (QM) Reports which are available to hospices. The seven HIS process measures are also available by visiting the data catalogue at *https://data.cms.gov/provider-data/topics/hospice-care.* We sought public comment on the technical correction to the regulation at § 418.312(b) effective October 1, 2021.

We received several comments on the proposal to remove the seven ''Hospice Item Set process measures'' from the HQRP beginning FY 2022. A summary of the comments and our responses to those comments appears below:

Comment: The majority of commenters supported the removal of the seven HIS process measures. Several commenters opposed removing the seven HIS process measures, at least prior to implementation of HOPE. These commenters believed that the existing process measures provide more valuable and transparent information about hospice performance than the HIS Comprehensive Assessment composite measure. Finally, some commenters recommended both removing the seven individual HIS process measures and retiring the HIS Comprehensive Assessment measure. These commenters suggested that retiring the composite measure would reduce provider burden.

Response: We appreciate the support for this proposal. In response to the concerns raised by those opposing the removal of seven HIS process measures, we would like to emphasize that all but one of the seven HIS measures are topped out individually and one HIS measure is almost topped out and shows insignificant variability between hospices. The 7 HIS measures credited hospices when any of these measures were performed regardless of the individual patient. In contrast, the HIS Comprehensive Assessment Measure measures whether a hospice assesses each patient on the 7 HIS measures. This distinction is important since it explains why the individual HIS

[8] The National Consensus Project Guidelines expand on the eight domains of palliative care in the 3rd edition and include clinical and organizational strategies, screening and assessment elements, practice examples, tools and resources. The guidelines were developed by the National Consensus Project for Quality Palliative Care, comprising 16 national organizations with extensive expertise in and experience with palliative care and hospice, and were published by the National Coalition for Hospice and Palliative Care. Journal of Hospice & Palliative Nursing: December 2018—Volume 20—Issue 6—p 507.

[9] MedPAC. (2020). *Chapter 12: Hospice Services. http://medpac.gov/docs/default-source/reports/mar20_medpac_ch12_sec.pdf.*

measures can be topped out but when measured together as a group, or composite, that is required on each patient in order to get credit for the measure, the HIS Comprehensive Assessment Measure shows variability and meets public reporting standards. This distinction explains why most hospices receive the maximum possible score on each of the 7 HIS measures, but not on the HIS Comprehensive Assessment Measure. As such, the individual measures have a limited ability to differentiate hospices. In contrast, the HIS Comprehensive Assessment Measure shows that hospices need to improve on providing a comprehensive set of assessments on each patient at admission and supports why it continues to be a useful HQRP measure.

While we consider it a success that hospices are assessing the care processes included in the 7 HIS measures, hospices have improved since 2014 to the point that these 7 individual HIS measures no longer differentiate quality of care between hospices and need to be retired as individual quality measures and thereby removed from the HQRP. Now that we reached that milestone, we need to recognize that there is a need to focus on assessing the 7 HIS measures to each patient at admission, which is what the HIS Comprehensive Assessment Measure addresses. It more closely aligns with the intent of the Hospice CoPs at Title 42 Part 418.54 that require a comprehensive assessment on each patient. This is why the HIS Comprehensive Assessment Measure provides valuable and transparent information about hospice performance. Patients electing to receive hospice services should expect quality care and a comprehensive assessment of their needs at admission, which the HIS Comprehensive Assessment Measure reflects. While the transition from the HIS to HOPE will eventually enable the HQRP to be more robust, we should not wait to seek improvement on this composite measure as an indicator of quality. This supports why we must remove the 7 HIS measures now in favor of the one more meaningful measure.

Finally, we support minimizing provider burden while maintaining quality measures that provide valuable information to providers and consumers about hospice quality. The variability shown in the HIS Comprehensive Assessment measure continues to provide useful information that allows patients and families to differentiate hospices and help select the best providers for their care.

Comment: MedPAC recommended that CMS consider removing the HIS Comprehensive Assessment Measure because the scores suggest the composite measure is limited in distinguishing provider quality. The comment suggested that the HIS Comprehensive Assessment measure would be likely to top out due to high scoring trends among hospices.

Response: We appreciate MedPAC raising this concern. We recognize that the HIS Comprehensive Assessment Measure reflects high scores and is improving over time, which may cause the measure to also become topped out in the future.[10] However, we believe that the single measure currently continues to show sufficient variability to differentiate hospices and therefore provides value to patients, their families, and providers. Further, the HIS Comprehensive Assessment Measure reflects the Hospice CoPs for comprehensive assessments performed at admission, which is a critical time to determine the plan of care. Its removal would not only leave HQRP without this important admission quality of care measure but also result in HQRP having only two claims-based measures, HCI and HVLDL, and the CAHPS Hospice Survey. It is these four quality measures, the HIS Comprehensive Assessment Measure, HCI, HVLDL, and CAHPS Hospice Survey that make up the FY 2022 HQRP requirements. These four measures cover hospice care throughout the hospice stay. The HIS Comprehensive Assessment Measure covers care at admission. HCI covers care throughout the hospice stay. HVLDL covers care during discharge and the CAHPS Hospice Survey covers the caregiver experience of hospice care. They complement each other and further support the need for each measure in the HQRP. We will continue to monitor the HIS Comprehensive Assessment Measure performance and consider if removal or refinements would be appropriate in the future.

Final Decision: In this final rule, we are not making any revisions to the HIS Comprehensive Assessment Measure. We are finalizing our proposal to remove the seven individual HIS process measures from the HQRP, no longer publicly reporting them as individual measures on Care Compare beginning with FY 2022. In addition, we will remove the ''7 measures that make up the HIS Comprehensive Assessment Measure'' section of Care Compare, which displays the seven HIS measures. These will be effective no earlier than May 2022. Hospice providers, must report HIS data used for the HIS Comprehensive Assessment Measure, in order to meet the requirements for compliance with the HQRP.

3. Addition of a ''Claims-Based Index Measure'', the Hospice Care Index

We proposed the addition of a new hospice quality measure, called the Hospice Care Index (HCI), to HQRP. The HCI will provide more information to better reflect several processes of care during a hospice stay, and better empower patients and family caregivers to make informed health care decisions. The HCI is a single measure comprising ten indicators calculated from Medicare claims data. The index design of the HCI simultaneously monitors all ten indicators. Collectively these indicators represent different aspects of hospice service and thereby characterize hospices comprehensively, rather than on just a single care dimension. Therefore, the HCI composite yields a more reliable provider ranking.

The HCI indicators, through the composite, will add new information to HQRP that was either directly recommended for CMS to publicly report by Federal stakeholders [11] [12] or identified as areas for improvement during information gathering activities. Furthermore, each indicator represents either a domain of hospice care recommended by leading hospice and quality experts [13] for CMS to publicly report, or a requirement included in the hospice CoPs. The indicators required to calculate the single composite are discussed in the ''Specifications for the HCI Indicators Selected'' section. These specifications list all the information required to calculate each indicator, including the numerator and denominator definitions, different thresholds for receiving credit toward the overall HCI score, and explanations for those thresholds. Indicators reflect practices or outcomes hospices should pursue, thereby awarding points based on the criterion. The HCI scoring example in Table 8 illustrates how points are awarded based on meeting the criterion of the indicator. For example, Gaps in Skilled Nursing Visits have a criterion of ''lower than the 90th percentile,'' and supports the hospice CoPs that require an assessment of the patient and caregiver needs as well as

[10] MedPAC. (2020). Chapter 11: Hospice Services. *http://www.medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf?sfvrsn=0.*

[11] 2019: Vulnerabilities in Hospice Care (Office of the Inspector General).

[12] Report to Congress: Medicare Payment Policy (March 2019) MEDPAC.

[13] 2019: Vulnerabilities in Hospice Care (Office of the Inspector General).

implementation of the plans of care. Other indicators, such as nurse visits (RN and LPN) on weekends or near death, have a criterion of ''higher than the 10th percentile,'' identifying hospice care delivery during the most vulnerable periods during a hospice stay.

Each indicator equally affects the single HCI score, reflecting the equal importance of each aspect of care delivered from admission to discharge. A hospice is awarded a point for meeting each criterion for each of the 10 indicators. The sum of the points earned from meeting the criterion of each indictor results in the hospice's HCI score, with 10 as the highest possible score. The ten indicators, aggregated into a single HCI score, convey a broad overview of the quality of the provision of hospice care services and validates well with CAHPS Willingness to Recommend and Rating of this Hospice. Skilled nursing visit data for indicators 2, 8, and 9 (described below) uses revenue center code 055X, which includes both RN and LPN visits for consistency with other indications for HCI.

The HCI will help to identify whether hospices have aggregate performance trends that indicate higher or lower quality of care relative to other hospices. Together with other measures already publicly reported in the HQRP, HCI scores will help patients and family caregivers choose between hospice providers based on the factors that matter most to them. Additionally, creating a comprehensive quality measure capturing a variety of related care processes and outcomes in a single metric will provide consumers and providers an efficient way to assess the overall quality of hospice care, which can be used to meaningfully and easily compare hospice providers to make a better-informed health care decision.

The HCI will complement the existing HIS Comprehensive Measure and does not replace any existing reported measures. Both the HCI and the HIS Comprehensive Measure are composite measures in that they act as single measures that capture multiple areas of hospice care. Because the indicators comprising the HCI differ in data source from the HIS Comprehensive Measure, the HCI and the HIS Comprehensive Measure can together provide a meaningful and efficient way to inform patients and family caregivers while supporting their selection of hospice care providers. As a claims-based measure, the HCI measure will not impose any requirements for collection of new information. To learn more about the background of the HCI, please watch this video: *https://youtu.be/by68E9E2cZc.*

a. Measure Importance

The FY 2019 Hospice Wage Index and Payment Rate Update final rule (83 FR 38622) introduced the Meaningful Measure Initiative to hospice providers to identify high priority areas for quality measurement and improvement. The Meaningful Measure Initiative areas are intended to increase measure alignment across programs and other public and private initiatives. Additionally, the initiative points to high priority areas where there may be informational gaps in available quality measures. The initiative helps guide our efforts to develop and implement quality measures to fill those gaps and develop those concepts towards quality measures that meet the standards for public reporting. The goal of HQRP quality measure development is to identify measures from a variety of data sources that provide a window into hospice care services throughout the dying process, fit well with the hospice business model, and meet the objectives of the Meaningful Measures initiative.

To that end, the HCI will add value to the HQRP by filling informational gaps in aspects of hospice service not addressed by the current measure set. Consistent with the Meaningful Measure Initiative, we conducted a number of information gathering activities to identify informational gaps. Our information gathering activities included soliciting feedback from hospice stakeholders such as providers and family caregivers; seeking input from hospice and quality experts through a Technical Expert Panel (TEP); interviews with hospice quality experts; considering public comments received in response to previous solicitations on claims-based hospice quality initiatives; and a review of quality measurement recommendations offered by the HHS Office of Inspector General (OIG), MedPAC, and the peer-reviewed literature.

We found that hospices currently underutilize HQRP measures to inform their quality improvement, mainly because of gaps in relevant quality information within the HQRP measure set. In particular, the existing HQRP measure set, calculated using data collected from the HIS and the CAHPS Hospice survey, does not assess quality of hospice care during a hospice election (between admission and discharge). Moreover, the current measure set does not directly address the full range of hospice services or outcomes. Therefore, we have identified a need for a new quality measure to address this gap and reflect care delivery processes during the hospice stay using available data without increasing data collection burden.

Claims data are the best available data source for measuring care during the hospice stay and present an opportunity to bridge the quality measurement gap that currently exists between the HIS and CAHPS Hospice Survey. Medicare claims are administrative records of health care services provided and payments which Medicare (and beneficiaries as applicable) made for those services. Claims are a rich and comprehensive source of many care processes and aspects of health care utilization. As such, they are a valuable source of information that can be used to measure the quality of care provided to beneficiaries for several reasons:

- Claims data are readily available and eliminates provider burden for implementation, as opposed to data collection through patient assessments or surveys, which require additional effort from clinicians, patients, and family caregivers before they can be submitted and used by CMS.
- Claims data are collected based on the actual care delivered, providing a more direct reflection of care delivery decisions and actions than patient assessments or surveys.
- Claims data are considered a reliable source of standardized data about the services provided, because providers must comply with Medicare payment and claims processing policy.

CMS already publicly reports several pieces of information derived from hospice claims data in the HQRP on Care Compare, including (i) the levels of care provided by the hospice, (ii) the primary diagnoses of patients served by the hospice, (iii) the location of hospice service provided, and (iv) the hospice's average daily census.

In the FY2018 Hospice Wage Index & Payment Rate proposed rule (82 FR 20750), we solicited public comment on two high-priority claims-based measure concepts being considered at the time, one which looked at transitions from hospice and another which examined access to higher levels of hospice care. In response to this solicitation, CMS received public comments highlighting the potential limitations of a single concept claims-based measure. In particular, a single-concept claims-based measure may not adequately account for all relevant circumstances that might influence a hospice's performance. While external circumstances could justify a hospice's poor performance on a single claims-based indicator, it would be unlikely for external circumstances to impact

multiple claims-based indicators considered simultaneously. Therefore, the result of a multi-indicator claims-based index, such as HCI, is more likely to differentiate hospices than a single claims-based indicator. Taking this public feedback into consideration, we designed the HCI and developed specifications based on simulated reporting periods.

b. Specifications for the HCI Indicators Selected

Specifications for the ten indicators required to calculate the single HCI score are described in this section. These component indicators reflect various elements and outcomes of care provided between admission and discharge. The HCI uses information from all ten indicators to collectively represent a hospice's ability to address patients' needs, best practices hospices should observe, and/or care outcomes that matter to consumers. Each indicator is a key component of the HCI measure that we proposed, and all ten are necessary to derive the HCI score. We use analytics, based on a variety of data files, to specify the indicators and measure. These data files include:

- Medicare fee-for-service (FFS) hospice claims with through dates on and between October 1, 2016 and September 30, 2019 to determine information such as hospice days by level of care, provision of visits, live discharges, hospice payments, and dates of hospice election.
- Medicare fee-for-service inpatient claims with through dates on and between January 1, 2016 and December 31, 2019 to determine dates of hospitalization.
- Medicare beneficiary summary file to determine dates of death.
- Provider of Services (POS) File to examine trends in the scores of the HCI and its indicators, including by decade by which the hospice was certified for Medicare, ownership status, facility type, census regions, and urban/rural status.
- CAHPS Hospice Survey to examine alignment between the survey outcomes and the HCI.

We acquired all claims data from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC). We obtained the hospice claims and the Medicare beneficiary summary file in May 2020, and the inpatient data in August 2020. We obtained the POS file data via: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services.* We obtained the Hospice-aggregate CAHPS Hospice Survey outcome data via: *https://data.cms.gov/provider-data.* We performed analyses using Stata/MP Version 16.1.

Table 7 indicates the number of hospice days, hospice claims, beneficiaries enrolled in hospices and hospices with at least one claim represented in each year of our analysis. Analysis for each year was based on the FY calendar. For example, FY 2019 covers claims with dates of services on or between October 1, 2018 and September 30, 2019. For these analyses, we exclude claims from hospices with 19 or fewer discharges [14] within a FY. The table reports the sample size before and after exclusion.[15]

TABLE 7: Sample Size for Analyses by Federal Fiscal Year (FY)

	FY 2018		FY 2019	
Excluding claims from hospices with <20 discharges	**Before Exclusion**	**After Exclusion**	**Before Exclusion**	**After Exclusion**
Number of hospice days represented	106,406,018	105,750,624	113,762,656	113,085,444
Number of claims	4,775,310	4,747,725	5,048,355	5,019,848
Number of beneficiaries represented	1,522,290	1,515,186	1,569,350	1,562,003
Number of hospices represented	4,623	4,004	4,796	4,155

The rest of this section presents the component indicators and their specifications. Although we describe each component indicator separately, the HCI is a composite that can only be calculated using all 10 indicators combined. We believe that, composed of this set of ten indicators, the HCI will strengthen the HQRP by comprehensively, reflecting hospices' performance across all ten indicators.

(1). Indicator One: Continuous Home Care (CHC) or General Inpatient (GIP) Provided

Medicare Hospice Conditions of Participation (CoPs) require hospices to be able to provide both CHC and GIP levels of care, if needed to manage more intense symptoms.[16] [17] However, a 2013 OIG report [18] found that 953 hospice programs did not provide any GIP level of care services, and it was unclear if dying patients at such hospices were receiving appropriate pain control or symptoms management (a similar concern exists for hospice services at the CHC level). To consider the provision of adequate services needed to manage patients' symptoms, the HCI measure includes an indicator for whether hospice programs provided any CHC or GIP service days. This indicator identifies hospices that provided at least

[14] We count discharges as any claim with a discharge status code other than ''30'' (which is defined as ''Still Patient'').

[15] Another exclusion was made prior to reporting the numbers in Table B.1. We exclude all claims for a beneficiary if a beneficiary ever had two overlapping hospice days on separate claims. For FY 2019 this removes 5,212,319 hospice days that come from 218,420 claims and 33,009 beneficiaries.

[16] See Special coverage requirements, Title 42, Chapter IV, Subchapter B, Part 418, § 418.204. *https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A3.0.1.1.5#se42.3.418_1204.*

[17] See Payment procedures for hospice care, Title 42, Chapter IV, Subchapter B, Part 418, § 418.302. *https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A3.0.1.1.5#se42.3.418_1302.*

[18] Office of Inspector General. (2013). *Medicare Hospice: Use of General lnpatient Care. https://oig.hhs.gov/oei/reports/oei-02-10-00490.pdf.*

one day of hospice care under the CHC or the GIP levels of care during the period examined. The provision of CHC and GIP is identified on hospice claims by the presence of revenue center codes 0652 (CHC) and 0656 (GIP).

The specifications for Indicator One, CHC or GIP services provided, are as follows:

- Numerator: The total number of CHC or GIP services days provided by the hospice within a reporting period.
- Denominator: The total number of hospice service days provided by the hospice at any level of care within a reporting period.
- Index Earned Point Criterion: Hospices earn a point towards the HCI if they provided at least one CHC or GIP service day within a reporting period.

(2). Indicator Two: Gaps in Skilled Nursing Visits

The OIG has found instances of infrequent visits by nurses to hospice patients.[19] To assess patients' receipt of nurse visits as outlined in the plan of care, one HCI indicator examines hospices that have a high rate of patients who are not seen at least once a week by nursing staff. This indicator includes both RN and LPN visits to recognize the frequency of skilled nursing visits and to maintain consistency in HCI when using revenue center code 055X.

This indicator identifies whether a hospice is below the 90th percentile in terms of how often hospice stays of at least 30 days contain at least one gap of eight or more days without a nursing visit. Days of hospice service are identified based on the presence of revenue center codes 0651 (routine home care (RHC)), 0652 (CHC), 0655 (inpatient respite care (IRC)), and 0656 (GIP) on hospice claims. We identify the dates billed for RHC, IRC, and GIP by examining the corresponding revenue center date (which identifies the first day in the sequence of days by level of care) and the revenue center units (which identify the number of days (including the first day) in the sequence of days by level of care). We identify the dates billed for CHC by examining the revenue center date.[20] We define a hospice stay by a sequence of consecutive days for a particular beneficiary that are billed under the hospice benefit. A gap of at least 1 day without hospice ends the sequence. For this indicator, we identified hospice stays that included 30 or more consecutive days of hospice. Once we identified those hospice stays, we examined the timing of the provision of nursing visits within those stays. We identified nursing visits if we observed any of the following criteria:

- The presence of revenue center code 055x (Skilled Nursing) on the hospice claim. The date of the visit is recorded in the corresponding revenue center date.
- The presence of revenue code 0652 (CHC) on the hospice claim. Days billed as CHC require more than half the hours provided be nursing hours.
- The presence of revenue code 0656 (GIP) on the hospice claim. We assume that days billed as GIP will include nursing visits. We make that assumption instead of looking at the visits directly because Medicare does not require hospices to record all visits on the claim for the GIP level of care.

If within a hospice stay, we find eight or more consecutive days where no nursing visits are provided, no CHC is provided, and no GIP is provided, then we identify the hospice stay as having a gap in nursing visits greater than 7 days. This indicator helps the HCI to capture patients' receipt of skilled nursing visits and direct patient care, which is an important aspect of hospice care. For each hospice, we divide the number of stays with at least one gap of eight or more days without a nursing visit (for stays of 30 or more days) by the number of stays of 30 or more days. We only consider the days within the period being examined.

The specifications for Indicator Two, Gaps in Skilled Nursing Visits, are as follows:

- Numerator: The number of elections with the hospice where the patient experienced at least one gap between nursing visits exceeding 7 days, excluding hospice elections where the patient elected hospice for less than 30 days within a reporting period.
- Denominator: The total number of elections with the hospice, excluding hospice elections where the patient elected hospice for less than 30 days within a reporting period.
- Index Earned Point Criterion: Hospices earn a point towards the HCI if their individual hospice score for gaps in skilled nursing visits greater than 7 days falls below the 90th percentile ranking among hospices nationally.

(3). Indicator Three: Early Live Discharges

Prior work has identified various concerning patterns of live discharge from hospice. High rates of live discharge suggest concerns in hospices' care processes, their advance care planning to prevent hospitalizations, or their discharge processes.[21] As MedPAC noted,[22] ''Hospice providers are expected to have some rate of live discharges because some patients change their mind about using the hospice benefit and dis-enroll from hospice or their condition improves and they no longer meet the hospice eligibility criteria. However, providers with substantially higher percent of live discharge than their peers could signal a potential concern with quality of care or program integrity. An unusually high rate of live discharges could indicate that a hospice provider is not meeting the needs of patients and families or is admitting patients who do not meet the eligibility criteria.''

Our live discharge indicators included in the HCI, like MedPAC's, comprise discharges for all reasons. They include instances where the patient was no longer found terminally ill and revocations due to the patient's choice. MedPAC explains their rationale for including all discharge as follows:[23]

''Some stakeholders argue that live discharges initiated by the beneficiary—such as when the beneficiary revokes his or her hospice enrollment—should not be included in a live-discharge measure because, some stakeholders assert, these discharges reflect beneficiary preferences and are not in the hospice's control. Because beneficiaries may choose to revoke hospice for a variety of reasons, which in some cases are related to the hospice provider's business practices or quality of care, we include revocations in our analysis.''

This indicator identifies whether a hospice is below the 90th percentile in terms of the percentage of live discharges that occur within 7 days of hospice admission during the fiscal year examined. Live discharges occur when the patient discharge status code on a hospice claim *does not* equal a code from the following list: ''30'', ''40'', ''41'', ''42'', ''50'', ''51''. We measure whether a live discharge occurs during the first 7 days of hospice by looking at a patient's lifetime length of stay in

[19] Office of Inspector General. (2019). *Hospice Deficiencies Pose Risks to Medicare Beneficiaries. https://oig.hhs.gov/oei/reports/oei-02-17-00020.pdf?utm_source=summary-page&utm_medium=web&utm_campaign=OEI-02-17-00020-PDF.*

[20] Hospices bill each day of CHC on a separate line item on the hospice claim.

[21] Teno J.M., Bowman, J., Plotzke, M., Gozalo, P.L., Christian, T., Miller, S.C., Williams, C., & Mor, V. (2015). Characteristics of hospice programs with problematic live discharges. Journal of Pain and Symptom Management, 50, 548–552. doi: 10.1016/j.jpainsymman.2015.05.001.

[22] MedPAC. (2020). *Chapter 12: Hospice Services. http://medpac.gov/docs/default-source/reports/mar20_medpac_ch12_sec.pdf.*

[23] MedPAC. (2020). *Chapter 12: Hospice Services. http://medpac.gov/docs/default-source/reports/mar20_medpac_ch12_sec.pdf.*

hospice.[24] For each hospice, we divide the number of live discharges in the first 7 days of hospice by the number of live discharges. Live discharges are assigned to a particular reporting period based on the date of the live discharge (which corresponds to the through date on the claim indicating the live discharge).

The specifications for Indicator Three, Early Live Discharges, are as follows:

- Numerator: The total number of live discharges from the hospice occurring within the first 7 days of hospice within a reporting period.
- Denominator: The total number of all live discharge from the hospice within a reporting period.
- Index Earned Point Criterion: Hospices earn a point towards the HCI if their individual percentage of live discharges on or before the seventh day of hospice falls below the 90th percentile ranking among hospices nationally.

(4). Indicator Four: Late Live Discharges

The rate of live discharge that occurred 180 days or more after hospice enrollment identifies another potentially concerning pattern of live discharge from hospice. Both indicator three and indicator four of the HCI recognize concerning patterns of live discharge impacting patient experience and quality of care. MedPAC, in descriptive analyses of hospices exceeding the Medicare annual payment cap, noted that ''if some hospices have rates of discharging patients alive that are substantially higher than most other hospices it raises concerns that some hospices may be pursuing business models that seek out patients likely to have long stays who may not meet the hospice eligibility criteria''.[25] Because of quality implications for hospices who pursue such business models, the live discharge after long hospice enrollments was included in the index.

This indicator identifies whether a hospice is below the 90th percentile in terms of the percentage of live discharges that occur on or after the 180th day of hospice. Live discharges occur when the patient discharge status code *does not* equal a value from the following list: ''30'', ''40'', ''41'', ''42'', ''50'', ''51''. We measure whether a live discharge occurs on or after the 180th day of hospice by looking at a patient's lifetime length of stay in hospice. For each hospice, we divide the number of live discharges that occur on or after the 180th day of hospice by the number of live discharges. Live discharges are assigned to a particular reporting period based on the date of the live discharge (which corresponds to the through date on the claim).

The specifications for Indicator Four, Late Live Discharges, are as follows:

- Numerator: The total number of live discharges from the hospice occurring on or after 180 days of enrollment in hospice within a reporting period.
- Denominator: The total number of all live discharge from the hospice within a reporting period.
- Index Earned Point Criterion: Hospices earn a point towards the HCI if their individual hospice score for live discharges on or after the 180th day of hospice falls below the 90th percentile ranking among hospices nationally.

(5). Indicator Five: Burdensome Transitions (Type 1)—Live Discharges From Hospice Followed by Hospitalization and Subsequent Hospice Readmission

The Type 1 burdensome transitions reflects hospice live discharge with a hospital admission within 2 days of hospice discharge, and then hospice readmission within 2 days of hospital discharge. This pattern of transitions may lead to fragmented care and may be associated with concerning care processes. For example, Type 1 burdensome transitions may arise from a deficiency in advance care planning to prevent hospitalizations or a discharge process that does not appropriately identify a hospice patient whose conditions are stabilized prior to discharge.[26]

This indicator identifies whether a hospice is below the 90th percentile in terms of the percentage of live discharges that are followed by a hospitalization (within 2 days of hospice discharge) and then followed by a hospice readmission (within 2 days of hospitalization) during the FY examined. Live discharges occur when the patient discharge status code *does not* equal a value from the following list: ''30'', ''40'', ''41'', ''42'', ''50'', ''51''. Hospitalizations are found by looking at all fee-for-service Medicare inpatient claims. Overlapping inpatient claims were combined to determine the full length of a hospitalization (looking at the earliest from date and latest through date from a series of overlapping inpatient claims for a beneficiary). In order to be counted, the ''from'' date of the hospitalization had to occur no more than 2 days after the date of hospice live discharge.[27] From there, we found all beneficiaries that ended their hospitalization and were readmitted back to hospice no more than 2 days after the last date of the hospitalization. To calculate the percentage, for each hospice we divided the number of live discharges that are followed by a hospitalization (within 2 days of hospice discharge) and then followed by a hospice readmission (within 2 days of hospitalization) in a given reporting period by the number of live discharges in that same period.

The specifications for Indicator Five, Burdensome Transitions Type 1, are as follows:

- Numerator: The total number of live discharges from the hospice followed by hospital admission within 2 days, then hospice readmission within 2 days of hospital discharge within a reporting period.
- Denominator: The total number of all live discharge from the hospice within a reporting period.
- Index Earned Point Criterion: Hospices earn a point towards the HCI if their individual hospice score for Type 1 burdensome transitions falls below the 90th percentile ranking among hospices nationally.

(6). Indicator Six: Burdensome Transitions (Type 2)—Live Discharges From Hospice Followed by Hospitalization With the Patient Dying in the Hospital

Death in a hospital following live discharge in another concerning pattern in hospice use. Thus, we believe that indicators five and indicator six of the HCI are necessary to differentiate concerning behaviors affecting patient care. This indicator reflects hospice live discharge followed by hospitalization within 2 days with the patient dying in the hospital, referred to as Type 2 burdensome transitions. This pattern of transitions may be associated with a discharge process that does not appropriately assess the stability of a hospice patient's conditions prior to live discharge.[28]

This indicator identifies whether a hospice is below the 90th percentile in terms of the percentage of live

[24] That is, we are measuring the first seven days of hospice over a patient's lifetime and potentially across multiple hospice elections and fiscal years.

[25] MedPAC. (2020). *Chapter 12: Hospice Services. http://medpac.gov/docs/default-source/reports/mar20_medpac_ch12_sec.pdf.*

[26] For example, see: Teno J.M., Bowman, J., Plotzke, M., Gozalo, P.L., Christian, T., Miller, S.C., Williams, C., & Mor, V. (2015). Characteristics of hospice programs with problematic live discharges. Journal of Pain and Symptom Management, 50, 548–552. doi: 10.1016/j.jpainsymman.2015.05.001.

[27] For example, if the hospice discharge occurred on a Sunday, the hospitalization had to occur on Sunday, Monday, or Tuesday to be counted.

[28] For example, see: Teno J.M., Bowman, J., Plotzke, M., Gozalo, P.L., Christian, T., Miller, S.C., Williams, C., & Mor, V. (2015). Characteristics of hospice programs with problematic live discharges. Journal of Pain and Symptom Management, 50, 548–552. doi: 10.1016/j.jpainsymman.2015.05.001.

discharges that are followed by a hospitalization (within two days of hospice discharge) and then the patient dies in the hospital. Live discharges occur when the patient discharge status code *does not* equal a value from the following list: ''30'', ''40'', ''41'', ''42'', ''50'', ''51''. Hospitalizations are found by looking at all inpatient claims. Overlapping inpatient claims were combined to determine a full length of a hospitalization (looking at the earliest from date and latest through date from a series of overlapping inpatient claims). To be counted, the ''from'' date of the hospitalization had to occur no more than 2 days after the date of hospice live discharge. From there, we identified all beneficiaries whose date of death is listed as occurring during the dates of the hospitalization. To calculate the percentage, for each hospice we divided the number of live discharges that are followed by a hospitalization (within 2 days of hospice discharge) and then the patient dies in the hospital in a given FY by the number of live discharges in that same reporting period.

The specifications for Indicator Six, Burdensome Transitions Type 2, are as follows:

- Numerator: The total number of live discharges from the hospice followed by a hospitalization within 2 days of live discharge with death in the hospital within a reporting year.
- Denominator: The total number of all live discharge from the hospice within a reporting year.
- Index Earned Point Criterion: Hospices earn a point towards the HCI if their individual hospice score for Type 2 burdensome transitions falls below the 90th percentile ranking among hospices nationally.

(7). Indicator Seven: Per-Beneficiary Medicare Spending

Estimates of per-beneficiary spending are endorsed by NQF (#2158) [29] and publicly reported by CMS for other care settings. Because the Medicare hospice benefit pays a per diem rate, an important determinant of per-beneficiary spending is the length of election. MedPAC reported that nearly half of Medicare hospice expenditures are for patients that have had at least 180 or more days on hospice, and expressed a concern that some programs do not appropriately discharge patients whose medical condition makes them no longer eligible for hospice services, or, that hospices selectively enroll patients with non-cancer diagnoses and longer predicted lengths of stay in hospice.[30] The other determinant of per-beneficiary spending is the level of care at which services are billed. In a 2016 report, the OIG has expressed concern at the potentially inappropriate billing of GIP care.[31] For these reasons the HCI includes one indicator for per-beneficiary spending; lower rates of per beneficiary spending may identify hospices that provide efficient care at a lower cost to Medicare.

This indicator identifies whether a hospice is below the 90th percentile in terms of the average Medicare hospice payments per beneficiary. Hospice payments per beneficiary are determined by summing together all payments on hospice claims for a particular reporting year for a particular hospice. The number of beneficiaries a hospice serves in a particular year is determined by counting the number of unique beneficiaries on all hospice claims in the same period for a particular hospice. Medicare spending per beneficiary is then calculated by dividing the total payments by the total number of unique beneficiaries.

The specifications for Indicator Seven, Per-Beneficiary Medicare Spending, are as follows:

- Numerator: Total Medicare hospice payments received by a hospice within a reporting period.
- Denominator: Total number of beneficiaries electing hospice with the hospice within a reporting period.
- Index Earned Point Criterion: Hospices earn a point towards the HCI if their average Medicare spending per beneficiary falls below the 90th percentile ranking among hospices nationally.

(8). Indicator Eight: Skilled Nursing Care Minutes per Routine Home Care (RHC) Day

Medicare Hospice CoPs require a member of the interdisciplinary team to ensure ongoing assessment of patient and caregiver needs.[32] Nursing services require initial and ongoing assessment of patient family needs to ensure the successful preparation, implementation, and refinements for the plan of care. This also includes patient and caregiver education and training as appropriate to their responsibilities for the care and services identified in the plan of care. This indicator includes both RN and LPN visits to recognize the frequency of skilled nursing visits and to maintain consistency in HCI when using revenue center code 055X.

This indicator identifies whether a hospice is above the 10th percentile in terms of the average number of skilled nursing minutes provided on RHC days during the reporting period examined. We identify RHC days by the presence of revenue code 0651 on the hospice claim. We identify the dates of RHC service by the corresponding revenue center date (which identifies the first day of RHC) and the revenue center units (which identifies the number of days of RHC (including the first day of RHC)). We identify skilled nursing visits by the presence of revenue code 055x (Skilled Nursing) on the claim. We count skilled nursing visits where the corresponding revenue center date overlaps with one of the days of RHC previously identified. We then count the minutes of skilled nursing visits by taking the corresponding revenue center units (that is, one unit is 15 minutes) and multiplying by 15. For each hospice, we sum together all skilled nursing minutes provided on RHC days and divide by the sum of RHC days.

The specifications for Indicator Eight, Skilled Nurse Care Minutes per RHC Day, are as follows:

- Numerator: Total skilled nursing minutes provided by a hospice on all RHC service days within a reporting period.
- Denominator: The total number of RHC days provided by a hospice within a reporting period.
- Index Earned Point Criterion: Hospices earn a point towards the HCI if their individual hospice score for Skilled Nursing Minutes per RHC day falls above the 10th percentile ranking among hospices nationally.

(9). Indicator Nine: Skilled Nursing Minutes on Weekends

Our regulations at § 418.100(c)(2) require that ''[n]ursing services, physician services, and drugs and biologicals . . . be made routinely available on a 24-hour basis seven days a week''.[33] Fewer observed hospice

[29] National Quality Forum. (2013). *#2158 Payment-Standardized Medicare Spending Per Beneficiary (MSPB). https://www.qualityforum.org/Projects/c-d/Cost_and_Resource_Project/2158.aspx.*

[30] MedPAC. (2020). *Chapter 12: Hospice Services. http://medpac.gov/docs/default-source/reports/mar20_medpac_ch12_sec.pdf.*

[31] Office of Inspector General. (2016). *Hospices Inappropriately Billed Medicare Over $250 Million for General Inpatient Care. https://oig.hhs.gov/oei/reports/oei-02-10-00491.pdf.*

[32] See Condition of participation: Interdisciplinary group, care planning, and coordination of services, Title 42, Chapter IV, Subchapter B, Part 418, § 418.56 (*https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A3.0.1.1.5#se42.3.418_156*) and Condition of participation: Hospice aide and homemaker services, Title 42, Chapter IV, Subchapter B, Part 418, § 418.76 (*https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A3.0.1.1.5#se42.3.418_176*).

[33] See § 418.100 (*https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A3.0.1.1.5#se42.3.418_1100*).

services on weekends (relative to that provided on weekdays) is not itself an indication of a lack of access. In fact, on weekends, patients' caregivers are more likely to be around and could prefer privacy from hospice staff. However, patterns of variation across providers could signal less service provider availability and access for patients on weekends. Thus, the HCI includes this indicator to further differentiate whether care is available to patients on weekends. To assess hospice service availability, this indicator includes minutes of care provided by skilled nurses on weekend RHC days. This indicator includes both RN and LPN visits to recognize the frequency of skilled nursing visits and to maintain consistency in HCI when using revenue center code 055X.

This indicator identifies whether a hospice is at or above the 10th percentile in terms of the percentage of skilled nursing minutes performed on weekends compared to all days during the reporting period examined. We identify RHC days by the presence of revenue code 0651 on the hospice claim. We identify the dates of RHC service by the corresponding revenue center date (which identifies the first day of RHC) and the revenue center units (which identifies the number of days of RHC (including the first day of RHC)). We identify skilled nursing visits by the presence of revenue code 055x (Skilled Nursing) on the claim. We count skilled nursing visits where the corresponding revenue center date overlaps with one of the days of RHC previously identified. We then count the minutes of skilled nursing visits by taking the corresponding revenue center units and multiplying by 15. For each hospice, we sum together all skilled nursing minutes provided on RHC days that occur on a Saturday or Sunday and divide by the sum of all skilled nursing minutes provided on all RHC days.

The specifications for Indicator Nine, Skilled Nursing Minutes on Weekends, are as follows:

- Numerator: Total sum of minutes provided by the hospice during skilled nursing visits during RHC services days occurring on Saturdays or Sunday within a reporting period.
- Denominator: Total skilled nursing minutes provided by the hospice during RHC service days within a reporting period.
- Index Earned Point Criterion: Hospices earn a point towards the HCI if their individual hospice score for percentage of skilled nursing minutes provided during the weekend is above the 10th percentile ranking among hospices nationally.

(10). Indicator Ten: Visits Near Death

The end of life is typically the period in the terminal illness trajectory with the highest symptom burden. Particularly during the last few days before death, patients (and caregivers) experience many physical and emotional symptoms, necessitating close care and attention from the hospice team and drawing increasingly on hospice team resources.[34 35 36] Physical symptoms of actively dying can often be identified within three days of death in some patients.[37]

This indicator identifies whether a hospice is at or above the 10th percentile in terms of the percentage of beneficiaries with a RN, LPN, and/or medical social services visit in the last 3 days of life. For this indicator, we first determine if a beneficiary was in hospice for at least 1 day during their last 3 days of life by comparing days of hospice enrollment from hospice claims to their date of death. We identify skilled nursing visits and medical social service visits by the presence of revenue code 055x (Skilled Nursing) and 056x (Medical Social Services) on the claim. We identify the dates of those visits by the revenue center date for those revenue codes. Additionally, we assume that days billed as GIP (revenue code 0656) will include skilled nursing visits. We make that assumption instead of looking at the visits directly because Medicare does not require hospices to record all visits on the claim for the GIP level of care. For each hospice, we divide the number of beneficiaries with skilled nursing or medical social service visits on a hospice claim during the last 3 days of life by the number of beneficiaries with at least 1 day of hospice during the last 3 days of life. In the proposed rule, the denominator description is discussed accurately, as the number of beneficiaries with at least one day of hospice during the last three days of life within a reporting period. However, the specification summary inaccurately reflected the number of decedent beneficiaries served by the hospice within a reporting period. In this final rule, we correct this error and replace the description of the denominator accurately as the number of beneficiaries with at least 1 day of hospice during the last 3 days of life within a reporting period.

The specifications for Indicator Ten, Visits Near Death, are as follows:

- Numerator: The number of decedent beneficiaries receiving a visit by a skilled nurse or social worker for the hospice in the last 3 days of the beneficiary's life within a reporting period.
- Denominator: The number of beneficiaries with at least 1 day of hospice during the last 3 days of life within a reporting period.
- Index Earned Point Criterion: Hospices earn a point towards the HCI if their individual hospice score for percentage of decedents receiving a visit by a skilled nurse or social worker in the last 3 days of life falls above the 10th percentile ranking among hospices nationally.

(11). Hospice Care Index Scoring Example

As discussed during the NQF's January 2021 MAP meeting, the HCI summarizes information from ten indicators with each indicator representing key components of the hospice care received, recognizing care delivery and processes. Hospices receive a single HCI score, which reflects the information from all ten indicators. Specifically, a hospice's HCI score is based on its collective performance for the ten performance indicators detailed earlier, all of which must be included to calculate the score and meaningfully distinguish between hospices' relative performance. The HCI's component indicators are assigned a criterion determined by statistical analysis of an individual hospice's indicator score relative to national hospice performance. Table 8 illustrates how a hypothetical hospice's score is determined across all ten indicators, and how the ten indicators' scores determine the overall HCI score.

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[34] de la Cruz, M., et al. (2015). Delirium, agitation, and symptom distress within the final seven days of life among cancer patients receiving hospice care. Palliative & Supportive Care, 13(2): 211–216. doi: 10.1017/S1478951513001144.

[35] Dellon, E.P., et al. (2010). Family caregiver perspectives on symptoms and treatments for patients dying from complications of cystic fibrosis. Journal of Pain & Symptom Management, 40(6): 829–837. doi: 10.1016/j.jpainsymman.2010.03.024.

[36] Kehl, K.A., et al. (2013). A systematic review of the prevalence of signs of impending death and symptoms in the last 2 weeks of life. American Journal of Hospice & Palliative Care, 30(6): 601–616. doi: 10.1177/1049909112468222.

[37] Hui D et al. (2014). Clinical Signs of Impending Death in Cancer Patients. The Oncologist. 19(6):681–687. doi:10.1634/theoncologist.2013–0457.

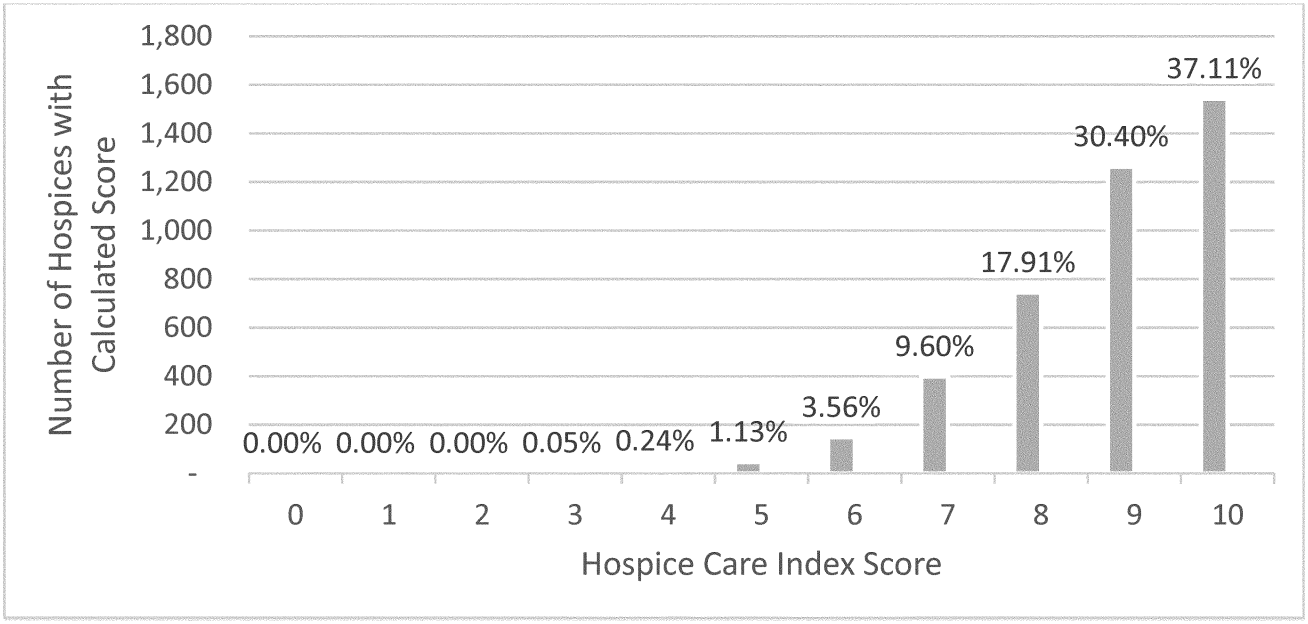
TABLE 8: Hospice Care Index Indicator Scoring Example

Name (Hospice Score Units)	Numerator	Denominator	Hospice Observed Score	National Average Score	Percentile Rank Among Hospices Nationally	Index Earned Point Criteria	Points Earned?	Points Awarded
Provided CHC/GIP (% days)	48	3,904	1.2%	0.9%	83	Hospice Score Above 0%	Yes	+1
Gaps in skilled nursing visits (% elections)	12	104	11.5%	5.9%	92	Below 90 Percentile Rank	No	0
Early live discharges (% live discharges)	3	27	11.1%	7.7%	75	Below 90 Percentile Rank	Yes	+1
Late live discharges (% live discharges)	14	27	51.9%	37.3%	84	Below 90 Percentile Rank	Yes	+1
Burdensome transitions, Type 1 (% live discharges)	4	27	14.8%	8.7%	77	Below 90 Percentile Rank	Yes	+1
Burdensome transitions, Type 2 (% live discharges)	0	27	0.0%	2.7%	1	Below 90 Percentile Rank	Yes	+1
Per-beneficiary Medicare spending (U.S. dollars $)	$2,322,657	256	$9,073	$12,959	22	Below 90 Percentile Rank	Yes	+1
Skilled nursing care minutes per routine home care day (minutes)	44,100	6,985	6.3	16.0	2	Above 10 Percentile Rank	No	0
Skilled nursing minutes on weekends (% minutes)	9,090	157,230	5.8%	9.4%	17	Above 10 Percentile Rank	Yes	+1
Visits near death (% decedents)	147	151	97.4%	94.5%	46	Above 10 Percentile Rank	Yes	+1
						Hospice Care Index Total Score =		**8**

c. Measure Reportability, Variability, and Validity

As part of developing the HCI, we conducted reportability, variability, and validity testing using claims data from FY 2019. Reportability analyses found a high proportion of hospices (over 85 percent) that would yield reportable measure scores over 1 year (for more on reportability analysis, see section (2) Update on Use of Q4 2019 Data and Data Freeze for Refreshes in 2021.). Variability analyses confirmed that HCI demonstrates sufficient ability to differentiate hospices. Hospices' scores on the HCI can range from zero to ten. During measure testing, we observed that hospices achieved scores between three and ten. In testing, 37.1 percent of hospices scored ten out of ten, 30.4 percent scored nine out of ten, 17.9 percent scored eight out of ten, 9.6 percent scored seven out of ten, and 5.0 percent scored six or lower, as shown in Figure 1.

Figure 1: Distribution of Hospice Care Index Scores, Federal Fiscal Year 2019



Source: 100% Medicare hospice claims, Federal Fiscal Year 2019.

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Validity analyses showed that hospices' HCI scores align with family caregivers' perceptions of hospice quality, as measured by CAHPS Hospice survey responses (NQF endorsed quality measure #2651). Hospices with higher HCI scores generally achieve better caregiver ratings as measured by CAHPS Hospice scores, and hospices with lower HCI scores generally achieve poorer CAHPS Hospice scores. As measured by Pearson's correlation coefficients, the correlation between the CAHPS hospice overall rating and the HCI is +0.0675, and the correlation between the CAHPS hospice recommendation outcome and the HCI score is +0.0916. As such, HCI scores are consistent with CAHPS Hospice caregiver ratings, supporting the index as a valid measurement of hospice care.

We also conducted a stability analysis by comparing index scores calculated for the same hospice using claims from Federal FY 2017 and 2019. The analysis found that 82.8 percent of providers' scores changed by, at most, one point over the 2 years. These results serve as evidence of the measure's reliability by indicating that a hospice's HCI scores would not normally fluctuate a great deal from one year to the next.

d. Stakeholder Support

A TEP convened by our measure development contractor, in April 2020, provided input on this measure. Additionally, during the summer of 2020, CMS convened five listening sessions with national hospice provider organizations to discuss the HCI concept with the goals of engaging stakeholders and receiving feedback early in the measure's development. In October 2020, our contractor convened a workgroup of family caregivers whose family members have received hospice care to provide input on this measure concept from the family and caregiver perspective. Finally, the NQF Measures Application Partnership (MAP) met on January 11, 2021 and provided input to CMS. The MAP conditionally supported the HCI for rulemaking contingent on NQF endorsement. The ''2020–2021 MAP 2020 Final Recommendations'' can be found at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94893.*

Stakeholders were generally supportive of a quality measure based on multiple indicators using claims data for public reporting. Several hospice providers expressed support for the measure's ability to demonstrate greater variation in hospice performance than the component indicators taken individually. Hospice caregivers also welcomed the addition of new quality measures to the HQRP to better differentiate between hospices. In particular, family caregivers stated that there might be a need for several HCI indicators, such as nursing availability on weekends and average Medicare per-beneficiary spending, to be included on Care Compare as additional information.

Some stakeholders raised concerns that claims data may not adequately express the quality of care provided, and may be better suited as an indicator for program integrity or compliance issues. Hospice providers suggested that claims may lack sufficient information to adequately reflect individual patient

needs or the full array of hospice practices. In particular, claims do not fully capture patients' clinical conditions, patient and caregiver preferences, or hospice activities such as telehealth, chaplain visits, and specialized services such as massage or music therapy. After much consideration of the input received, we believe the benefits of adopting the HCI outweigh its limitations. The HCI is not intended to account for all potentially valuable aspects of hospice care, nor is it expected to entirely close the information gaps presently found in the HQRP. Rather, the HCI will serve as a useful measure to add value to the HQRP by providing more information to patients and family caregivers and better empowering them to make informed health care decisions. We view the HCI as an opportunity to add value to the HQRP, augmenting the current measure set with an index of indicators compiled from currently available claims data. This will provide new and useful information to patients and family caregivers without further burden to them, or to providers.

Stakeholders also suggested several valuable exploratory analyses, improvements for the indicators presented, and ideas for eventual public display for CMS to consider. We further refined the HCI based on this feedback, focusing on those indicators with the strongest consistency with CAHPS Hospice scores and/or which quality experts have identified as salient issues for measurement and observation. We also revised and refined how the HCI will be publicly displayed on Care Compare in response to family caregiver input.

e. Form, Manner and Timing of Data Collection and Submission

The data source for this HCI measure will be Medicare claims data that are already collected and submitted to CMS. We proposed and finalizing in the rule to begin reporting this measure using existing data items no earlier than May 2022. For more details, see section (3). Publicly Report the Hospice Care Index and Hospice Visits in the Last Days of Life Claims-based Measures.

In addition, to help hospices understand the HCI and their hospice's performance, we will revise the confidential QM report to include claims-based measure scores, including agency and national rates through the Certification and Survey Provider Enhanced Reports (CASPER) or its replacement system. The QM report will also include results of the individual indicators used to calculate the single HCI score, and provide details on the indicators and HCI overall score to support hospices in interpreting the information. The HCI indicators will be available by visiting the Provider Data Catalog at *https://data.cms.gov/provider-data/topics/hospice-care.*

We solicited public comment on the proposal to add the composite HCI measure to the HQRP starting in FY 2022. We also solicited comments on the proposal to add the HCI to the program for public reporting beginning no earlier than May 2022. We received many comments on these proposals. A summary of the comments we received regarding HCI and our responses to those comments appear below:

Comment: Several commenters expressed the importance of HCI for beneficiary and families that will give them information about care processes and add value to the available information about hospices that identifies aberrant practice when comparing hospices.

Response: We appreciate the support by comments recognizing the value HCI brings to consumers by providing more information not previously available about hospices. The HCI will add value to the HQRP by filling measurement gaps using existing data sources.

Comment: Many commenters appreciate the need for CMS to address program integrity or identify hospices with aberrant practices, and encouraged CMS to develop different measures that better reflect the holistic, interdisciplinary nature of hospice. Other comments also suggested that data already provided in PEPPER reports should not be included in HCI or that CMS should share the indicators in the PEPPER reports rather than implement the HCI quality measure to provide hospices the opportunity to implement continuous quality improvement activities.

Response: We recognize commenters' concern that HQRP measures reflect quality of care rather than program integrity issues. We believe HCI does reflect hospice quality because the HCI indicators were identified as quality issues by the Office of Inspector General,[38,39,40] the Medicare Payment Advisory Commission,[41 42 43] by peer reviewed articles, and our technical expert panel (TEP). Further, HCI like the other HQRP quality measures validates well with the CAHPS Hospice Survey ''willingness to recommend'', which signifies a quality measure useful for public reporting.

We also appreciate the suggestions to include HCI indicators in PEPPER reports rather than implement HCI. However, unlike PEPPER reports that are issued to hospices to support their compliance efforts related to potential improper payments, as part of the HQRP, the HCI will become information on Care Compare that beneficiaries, caregivers, or other stakeholders may consider as they make choices about end-of-life care.

Comment: Several comments suggested that CMS differentiate circumstances in which a patient refused a service measured by the HCI from circumstances in which the hospice did not offer the service to the patient. Other comments highlighted the possible impact of claims-based measures on rural and small providers because they may not capture care in rural communities or possibly identified as an outlier due to low volume.

Response: CMS acknowledges that patients have the right to refuse hospice services, and that some refusals are expected and appropriate. CMS expects hospices to honor patient wishes on a case-by-case basis. Thus, we do not anticipate service refusals to be concentrated among particular hospices, and as such do not expect refused visits to have an outsized effect on any hospice's performance on this measure. Several existing measures, such as the HIS-based HVWDII measure and its replacement HVLDL, also do not differentiate refused visits.

We also appreciate the comments expressing concern about the impact these measures may have on small and/

[38] Department of Health and Human Services, Office of Inspector General. (2013). Medicare hospice: Use of general inpatient care. Accessible via: *https://oig.hhs.gov/oei/reports/oei-02-10-00490.asp.*

[39] Department of Health and Human Services, Office of Inspector General. (2016). Medicare hospice: Hospices Inappropriately Billed Medicare Over $250 Million for General Inpatient Care. Accessible via: *https://oig.hhs.gov/oei/reports/oei-02-10-00491.asp.*

[40] Department of Health and Human Services, Office of Inspector General. (2019). Registered Nurses Did Not Always Visit Medicare Beneficiaries Homes at Least Once Every 14 Days to Assess the Quality of Care and Services Provided by Hospice Aides. Accessible via: *https://oig.hhs.gov/oas/reports/region9/91803022.pdf.*

[41] Medicare Payment Advisory Commission. March 2009 Report to the Congress: Medicare Payment Policy, ''Chapter 6: Reforming Medicare's hospice benefit.'' February 27, 2009. Accessible via: *http://www.medpac.gov/docs/default-source/reports/Mar09_Ch06.pdf?sfvrsn=0.*

[42] Medicare Payment Advisory Commission. March 2011 Report to the Congress: Medicare Payment Policy, ''Chapter 11: Hospice.'' March 15, 2011. Accessible via: *http://www.medpac.gov/docs/default-source/reports/Mar11_Ch11.pdf?sfvrsn=0.*

[43] Medicare Payment Advisory Commission. March 2020 Report to the Congress: Medicare Payment Policy Text, ''Chapter 12: Hospice Services.'' March 13, 2020. Accessible via: *http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch12_sec.pdf?sfvrsn=0.*

or rural hospices. We recognize that there are many regional variations in care delivery trends. We will monitor HCI score trends to identify whether any regional or size-based variations suggest a need for measure revision. However, population-based measures such as indicators on the HCI allow for hospice variation for an indicator while offering opportunities to earn points on other indicators. The points are earned without weighting to recognize the tradeoffs for each indicator's specifications.

Comment: Several comments recommended that CMS not implement HCI because the indicators seem to emphasize medical services, focused heavily on services provided by RNs/LPNs, or do not account for the full interdisciplinary group (for example, claims do not account for spiritual care). Some commenters questioned whether services provided by LPNs would be accounted for in the HCI indicators and many commenters requested that CMS clarify whether code 055X would be further differentiated between RN visits versus LPN visits for the indicators.

Response: We recognize that claims data do not include all the disciplines involved in the delivery of hospice care, such as the frequency and length of chaplain visits. While changing the data included in claims is outside the scope of this proposed measure, we believe that using the claims data that currently exists still provides new and useful information not currently available to patients, families, and caregivers with the existing HQRP measures. As we showed with the HVLDL claims-based measure, RN services correlate well with CAHPS data and therefore are important services to reflect hospice quality of care. The HCI serves as a useful step in addressing HQRP data gaps and providing useful information to consumers, even if it does not account for all potentially valuable data currently missing from HQRP. CMS will monitor data availability as well as measure performance, and may re-specify the measure if needed. If additional data points become available, CMS will consider modifying the measure in light of the new data. CMS' sub-regulatory Quality Measure Users' Manual on the CMS HQRP Current Measures web page will include specifications for each indicator and scoring for HVLDL, and the HIS Comprehensive Assessment measure (NQF #3235).

We appreciate the comments and request for clarification on whether LPNs are included in visits. Both RN and LPN visits are included on the hospice claim under revenue code 055X and as such, the HCI does include LPN visits for the indicator for all indicators that use revenue code 055X for consistency. This does not constitute a change to the requirements of the CoPs.

Comment: Several commenters stated that the HCI should focus on whether hospices are prepared to provide key services, rather than whether claims for those services were billed during a given reporting period. One way to approach this would be to use state survey data to identify hospices that are deficient and do not have contracts to provide GIP. This information would provide additional context to the claims data of whether a hospice provided CHC or GIP.

Response: We appreciate commenters' interest in having the HCI reflect how prepared hospices are to provide key services to patients. We believe that by measuring whether hospices actually provided CHC and GIP, the HCI will recognize the extent to which hospices both kept patients at home and recognized the need for inpatient care when necessary. In this way, these billing categories reflect actions taken to meet patients' needs during the reporting period. While we recognize the additional context that state survey data would provide, we believe the claims data used to calculate the HCI will provide valuable information to consumers on their own.

Comment: We received several comments out of scope of the proposal suggesting CMS allow for use of the spiritual care HCPCS code approved for Veteran Administration use. Some commenters requested that CMS expand billing codes for telehealth visits and recognize telehealth services within the HCI. Other commenters expressed concern that the HCI indicators do not take patient preferences into account, and that the HCI might incentivize hospices to standardize the types and amount of services provided rather than considering personal patient circumstances.

Response: We appreciate commenters' concerns that hospice providers continue to recognize and address the unique circumstances of hospice patients. At this time, the HCPCS code for spiritual care is not used on the hospice claim form (no revenue center exists to correspond to such code), and as such, cannot be applied to the HCI. Additionally, we did not propose to expand billing codes for telehealth services or patient preferences, and as such cannot include such services in the HCI. However, if additional Medicare hospice claims data points become available, we may consider modifying the measure in light of the new data. We are concerned hospices believe HCI may incentivize hospices to standardize the types or amount of services provided to patients and not individualize beneficiary care on a case-by-case basis at the end of life. CMS will continue to monitor for any aberrant behavior in regard to HCI and the care provided by hospices.

Comment: Several commenters would like more time and information to replicate the analysis for HCI. The commenters suggest a delay in publicly reporting or no earlier than May 2022, which would to allow time for internal analysis.

Response: We appreciate commenters' concerns that hospice providers do not believe they could replicate the indicators without more information. However, in the preamble of the FY 2022 Hospice proposed rule (86 FR 19700) and in this final rule is a description for each indicator including the rationale, numerator, denominator, exclusion criterion, and data sources. We believe the information provided in the proposed and final rule allows for commenters to replicate, with their own claims data, the indicators, thresholds, and points earned. The sub-regulatory Quality Measure Users' Manual will be posted on the HQRP Current Measures web page to provide measure specifications. We believe this information provides the detail needed, as with prior versions of the Quality Measure Users' Manual, to model and analyze HCI and its indicators. As discussed later in this section of the preamble, hospices will have access to preview reports in advance of publicly reporting HCI.

Comment: Many commenters offered suggestions to modify specific HCI indicators and expressed concerns about specific indicators rather than the HCI as a whole. Several commenters suggested that CMS adjust the thresholds for specific services, such as gaps in skilled nursing visits, and phase in the thresholds over time. Some commenters questioned how well the HCI differentiates between high-quality, average, and low-quality hospices. They encouraged CMS to conduct further analyses before finalizing the measure.

Response: We appreciate commenters' suggestions for modifications to the indicators, additional analyses to conduct, and requests to monitor the indicators. We also appreciate the concern that we avoid duplicating measures in the development of new measures based on assessment data, claims, or other available data sources. We conducted multiple analyses during the development of HCI to validate these indicators and determine

thresholds before selecting them for inclusion in the final HCI measure. We also shared the measure concept publicly and solicited stakeholder feedback, which we considered before finalizing the measure specifications. Our analyses showed that the HCI as currently defined does differentiate between hospices, as the range of HCI scores across hospices was found to be sufficiently large to highlight very high performing hospices, as well as identify the need for improvement in others. Additionally, the distribution of HCI scores aligns with caregivers' perceptions of hospice quality. As such, we have determined that the ten HCI indicators, taken together as currently defined, reflect a holistic view of hospice performance trends during a patient's stay.

Comment: Several commenters expressed concerns that the HCI will overlap with, or be duplicative of, HOPE-based measures.

Response: We appreciate commenters' concerns regarding the administrative burden in quality reporting. Because the HCI relies on claims data that are already collected by CMS, reporting claims-based measures places no additional burden for hospice providers or other stakeholders. In addition, the HCI and HOPE will complement each other, providing related but distinct information to providers and consumers to compare hospices.

Comment: Some commenters expressed concern that the HCI will become ''topped out,'' with 85 percent of hospices scoring a 7 or better, limiting the measure's ability to differentiate between hospices.

Response: We appreciate commenters' concerns that HQRP measures will not be able to adequately differentiate hospices if they become ''topped out.'' We also understand why commenters might expect process measures to be prone to ''topping out.'' CMS has taken this into consideration in designing the HCI measure. The design of the HCI ensures that the measure is very unlikely to become topped out. Each HCI indicator is scored based on comparative performance, with hospices receiving a point based on their performance relative to a national percentile threshold. Using percentile rankings derived from national performance, it is very unlikely for all hospices to receive the same score. Our analyses suggest that the scoring criteria ensure distributions of HCI scores that allow for differentiation between hospices in any given year. However, CMS will continue to monitor the HCI after implementation to ensure the measure reflects hospice quality, differentiates between hospices, and does not become topped out.

Final Decision: We are finalizing the proposal to add composite HCI measures to the HQRP as of FY 2022 and will monitor the measure. As discussed later in this section of the preamble, we will publicly report no earlier than May 2022.

4. Update on the Hospice Visits in the Last Days of Life (HVLDL) and Hospice Item Set V3.00

On August 13, 2020, we sought public comment in an information collection request to remove Section O ''Service Utilization'' (hereafter referred to as Section O) of the HIS discharge assessment. Removal of Section O is the sole change from HIS V2.01 and in effect eliminate the HVWDII quality measure pair. In Paperwork Reduction Act package (PRA), CMS–10390 (OMB control number: 0938–1153), we provided the HVLDL specifications and also proposed to replace the HVWDII measure pair with the HVLDL. This means that we will no longer report HVWDII with patient stays and will start publicly reporting HVLDL no earlier than May 2022. The Office of Management and Budget (OMB) approved the collection of information to remove Section O of the HIS expiring on February 29, 2024, (OMB Control Number: 0938–1153, CMS–10390). We direct the public to review the PRA at *https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10390* and HVWDII report at *https://www.cms.gov/files/document/hqrphospice-visits-when-death-imminent-testing-re-specification-reportoctober-2020.pdf.* As a claims-based measure, the HVLDL measure would not impose any new requirements for the collection of information.

The HVLDL measure, as a replacement, will continue to fill an important area in hospice care previously filled by the HVWDII measure pair. We discussed the analysis with a TEP convened by our measure development contractor in November 2019 and with the MAP, hosted by the NQF in December 2019 [44] for inclusion in the HQRP. During these meetings, the discussions reflecting on the analysis generally supported the replacement of HVWDII with a claims-based HVLDL measure. The November 2019 TEP report can be found in the downloads section at Hospice QRP Provider Engagement Opportunities and final recommendations and presentation of the HVLDL measure before NQF's MAP can be found at Quality Forum—Post-Acute Care, *https://www.qualityforum.org/Publications/2020/02/MAP_2020_Considerations_for_Implementing_Measures_Final_Report_-_PAC_LTC.aspx.*

OMB approved the proposal to replace the HVWDII measure with the HVLDL measure and remove Section O from the discharge assessment on February 16, 2021. The HIS V3.00 became effective on February 16, 2021 and expires on February 29, 2024; OMB control number 0938–1153.

We received several comments regarding the updates to the Hospice Visits in the Last Days of Life (HVLDL) and Hospice Item Set V3.00. A summary of the comments we received and our responses those comments are below:

Comment: Several comments support the re-specified HVLDL claims-based measure and the resulting reduction of burden, but expressed concern that the measure is limited to RN and medical social worker. Commenters stated that the measure should recognize the full spectrum of disciplines involved in hospice care. Some commenters requested that LPNs count for the measure, in addition to RNs. Other commenters stated that chaplain or spiritual services may be as important to patients as nursing services.

Response: As discussed in the CMS–10390 Supporting Statement published October, 23, 2020 and HIS V3.00 approved by OMB on February 16, 2021, we pursed a re-specification of the HVWDII measure concept using Medicare claims data because claims data also capture RN and medical social worker visits by hospice. While CMS agrees that all patient visits are meaningful, based on our analyses, we found that RN and medical social worker visits correlate well with the CAHPS quality measures for ''would recommend'' the hospice. HVLDL indicates the hospice provider's proportion of patients who have received visits from an RN or medical social worker (in-person) on at least two out of the final three days of the patient's life. While all patient visits are meaningful, only patients with visits on two different days during the last three days of life will count towards the numerator for this measure. These visits can be made by either the RN, the medical social worker, or both. We were interested in re-specifying the visit measure to better align with the SIA because, as we discussed in previous rules, patient needs typically surge as

[44] National Quality Forum. (2020). *MAP 2020 Considerations for Implementing Measures Final Report—PAC LTC. http://www.qualityforum.org/Publications/2020/02/MAP_2020_Considerations_for_Implementing_Measures_Final_Report_-_PAC_LTC.aspx.*

the end of life approaches and more intensive services are warranted. The provision of care would proportionately escalate to meet the increased clinical, emotional, and other needs of the patient and family.

Comment: Some commenters stated that the measure specifications would not adequately capture hospices' care activities. Some commenters suggested that the measure should allow for two visits occurring on the same day to meet the measure qualifications, as visits on the same day could address different patient needs, representing meaningful care on the part of the hospice. Other commenters requested that this measure recognize visits offered during CHC or GIP care. Some commenters stated that the measure should recognize telehealth visits in the last days of life, as circumstances such as the recent COVID–19 PHE may make in-person visits impossible or undesirable for patients or families.

Response: We agree that hospice care is interdisciplinary care delivered by clinical and non-clinical staff supporting the patient's plan of care. We also support hospices providing necessary visits in the last days of life such that two visits occurring on the same day may be necessary. However, as discussed in the CMS–10390 Supporting Statement published October 23, 2020 and HIS V3.00 approved by OMB on February 16, 2021, our analysis comparing HVWDII and HVLDL with CAHPS ''would recommend'' scores demonstrates that HVLDL results in higher validity and variability testing results compared to HVWDII. We found a stronger correlation coefficient with CAHPS ''would recommend'' scores for HVLDL than for HVWDII. This means that when visits by RNs or medical social workers occurred in at least two of the last three days of life, family and caregivers agree or positively correlate that they would recommend the hospice, more often when compared to HVWDII, on average. The literature strongly supported the focus on RNs and medical social workers in the revised measure.

Actively dying is a critical and unique time when in-person, skilled care is typically needed. HVLDL is defined for in-person visits. As with all quality measures, we are encouraging quality of care and as such hospices are expected to use in-person visits when visits are needed during these critical last days of life. We agree there are benefits to telehealth visits that supplement, not replace, in-person visits. If claims data are revised to include other disciplines, we may consider whether to include them in this measure. This measure does not recognize visits during CHC and GIP because these higher levels of care inherently require skilled visits per the COPs in accordance with § 418.110 and § 418.302.

Comment: Several comments requested that CMS clarify how ''the last three days of life'' would be calculated. Commenters expressed concern that definitions were unclear.

Response: The exclusion criteria used for HVWDII and now HVLDL criteria remain the same. The calculation of the last three days remain unchanged from the last three days documented in Section O of the HIS V2.00 that was used to calculate the HVWDII. Information defining the last three days has been included in the HIS Manuals since 2017. These specifications will now be contained in the revised HQRP QM User's Manual V4.00 located on the CMS HQRP Current measures web page. This information was also posted in the document ''Common Questions HQRP Claims-Based Measures_Feb.2021'' located in the Downloads section of the Hospice Item Set web page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.*

Specifically these three days are ''indicated by the day of death, the day prior to death, and two days prior to death.'' The day of death is the same as the date provided in A0270, Discharge Date. (or the day of death); One day prior to death is calculated as A0270 minus 1, and two days prior to death is calculated as A0270 minus 2. Full HVLDL specifications are also publicly available on the HQRP website at: *https://www.cms.gov/files/document/hospice-visits-last-days-life-hvldl-measure-specifications.pdf.*

5. Proposal To Revise § 418.312(b) Submission of Hospice Quality Reporting Program Data

To address the inclusion of administrative data, such as Medicare claims used for hospice claims-based measures like the HVLDL and HCI in the HQRP and correct technical errors identified in the FY 2016 and 2019 Hospice Wage Index and Payment Rate Update final rules, we proposed and finalize in this rule the regulation at § 418.312(b) by adding paragraphs (b)(1) through (3). Paragraph (b)(1) will include the existing language on the standardized set of admission and discharge items. Paragraph (b)(2) would require collection of Administrative Data, such as Medicare claims data, used for hospice quality measures to capture services throughout the hospice stay. And these data automatically meet the HQRP requirements for § 418.306(b)(2).

Paragraph (b)(3) is a technical correction to address errors identified in the FY 2016 and FY 2019 Hospice Wage Index and Payment Rate Update final rules, (80 FR 47186 and 83 FR 38636). In the FY 2016 Hospice final rule (80 FR 47186) adopted seven factors for measure removal, and in the FY 2019 Hospice final rule (83 FR 38636) adopted the eighth factor for measure removal. In those final rules, we referenced the measure removal factors in the preamble but inadvertently omitted them from the regulations text. Thus, these measure removal factors identify how measures are removed from the HQRP. Section 418.312(b)(3) would include the eight measure removal factors as follows:

CMS may remove a quality measure from the Hospice QRP based on one or more of the following factors:

(1) Measure performance among hospices is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

(2) Performance or improvement on a measure does not result in better patient outcomes.

(3) A measure does not align with current clinical guidelines or practice.

(4) The availability of a more broadly applicable (across settings, populations, or conditions) measure for the particular topic.

(5) The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(6) The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(7) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(8) The costs associated with a measure outweigh the benefit of its continued use in the program.

We did not receive comments on this proposal. We are finalizing in this rule the regulation at § 418.312(b) to add paragraphs (b)(1) through (3) to include administrative data as part of the HQRP, and correct technical errors identified in the FY 2016 and 2019 Hospice Wage Index and Payment Rate Update final rules.

6. Update Regarding the Hospice Outcomes & Patient Evaluation (HOPE) Development

As finalized in the FY 2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements final rule (84 FR 38484),

we are developing a hospice patient assessment instrument identified as HOPE. This tool is intended to help hospices better understand care needs throughout the patient's dying process and contribute to the patient's plan of care. It will assess patients in real-time, based on interactions with the patient. HOPE will support quality improvement activities and calculate outcome and other types of quality measures in a way that mitigates burden on hospice providers and patients. Our two primary objectives for HOPE are to provide quality data for the HQRP requirements through standardized data collection, and to provide additional clinical data that could inform future payment refinements.

We anticipate that HOPE will replace the HIS. While the HIS is a standardized mechanism for abstracting medical record data, it is not a patient assessment tool because HIS data are not collected during a patient assessment. HIS data collection ''consists of selecting responses to HIS items in conjunction with patient assessment activities or via abstraction from the patient's clinical record.'' (HIS Manual v.2.01). In contrast, HOPE is a patient assessment instrument, designed to capture patient and family care needs in real-time during patient interactions throughout the patient's hospice stay, with the flexibility to accommodate patients with varying clinical needs. HOPE will enable CMS and hospices to understand the care needs of people through the dying process, supporting provider care planning and quality improvement efforts, and ensuring the safety and comfort of individuals enrolled in hospice nationwide. HOPE will include key items from the HIS and demographics like gender and race. This approach to include key aspects of demographics supports hospice feedback provided in the FYs 2017 and 2018 Hospice Wage Index and Payment Rate Update final rule (81 FR 52171 and 82 FR 36669) and CMS' goals for a hospice assessment instrument, as stated in the FY 2018 Hospice Wage Index and Payment Rate Update final rule. The HOPE assessment instrument would facilitate communication among providers and measure the care of patient populations across settings. While the standardized patient assessment data elements for certain post-acute care providers required under the IMPACT Act of 2014 is not applicable to hospices, it makes reasonable sense to include some of those standardized elements that appropriately and feasibly apply to hospice. Some patients may move through the healthcare system to hospice so capturing and tracking key demographic and social risk factor items that apply to hospice may help CMS achieve our goals for continuity of care, overall patient care and well-being, interoperability, and health equity that are also discussed in this rule.

The draft of HOPE has undergone cognitive and pilot testing, and will undergo field testing to establish reliability, validity, and feasibility of the assessment instrument. We anticipate proposing HOPE in future rulemaking after testing is complete.

We will continue development of HOPE in accordance with the Blueprint for the CMS Measures Management System. Development of HOPE is grounded in extensive information gathering activities to identify and refine hospice assessment domains and candidate assessment items. We appreciate the industry's and national associations' engagement in providing input through information sharing activities, including listening sessions, expert interviews, key stakeholder interviews, and focus groups to support HOPE development. As CMS proceeds with field testing HOPE, we will continue to engage with stakeholders through sub-regulatory channels. In particular, we will continue to host HQRP Forums to allow hospices and other interested parties to engage with us on the latest updates and ask questions on the development of HOPE and related quality measures. We also have a dedicated email account, *HospiceAssessment@cms.hhs.gov,* for comments about HOPE. We will use field test results to create a final version of HOPE to propose in future rulemaking for national implementation. We will continue to engage all stakeholders throughout this process. We appreciate the support for HOPE and reiterate our commitment to providing updates and engaging stakeholders through sub-regulatory means. Future updates and engagement opportunities regarding HOPE can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HOPE.html.*

We received many comments about the HOPE update. A summary of these comments and our responses appear below:

Comments: Several commenters encouraged CMS to thoughtfully consider the implementation timeline for HOPE and the collection demographic and social risk factor data. The comments pointed out that the process for providers to adapt to the new tool requires at least 6 months or more. They noted the implementation of a new assessment instrument would be burdensome on both providers and EMR vendors.

Several commenters noted the potential for overlap in quality measures from HOPE and HCI or future measures. They encouraged CMS to eliminate any duplicative measures from HCI and HOPE, and to consider using HOPE data as the source for publicly reported information once it is implemented.

Response: We thank commenters for raising points for CMS to consider in advance of HOPE implementation. We appreciate commenters' concern for provider and vendor burden in implementing a new tool and encourage all key stakeholders to continue to stay informed and engaged through the HQRP Forums, Quarterly Updates, and listserv notifications.

7. Update on Quality Measure Development for Future Years

In the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52160), we finalized new policies and requirements related to the HQRP, including how we would provide updates related to the development of new quality measures. Information on the current HQRP quality measures can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.* In this proposed rule, we are continuing to provide updates for both HOPE-based and claims-based quality measure development.

To support new measure development, our contractor convened TEP meetings in 2020 to provide feedback on several measure concepts. In 2020, the TEP explored potential quality measure constructs that could be derived from HOPE and their specifications. Specifically, for HOPE-based measure development, the TEP focused on pain and other symptom outcome measure concepts that could be calculated from HOPE. Input from initial TEP workgroups held in spring 2020 informed follow-up information-gathering activities related to pain in general and neuropathic pain in particular. The 2020 Information Gathering Summary report is available at *https://www.cms.gov/files/document/12042020-information-gathering-oy1508.pdf.* During fall 2020, the TEP reviewed measure concepts focusing on pain and symptom outcomes that could be calculated from HOPE items.

The TEP supported further exploration and development of these measures. As described in the 2020 TEP Summary Report, the TEP generally

supports the following measure concepts that are calculated using HOPE items: Timely Reduction of Pain Impact, Reduction in Pain Severity, and Timely Reduction of Symptoms. The candidate measure Timely Reduction of Pain Impact reports the percentage of patients who experienced a reduction in the impact of moderate or severe pain. HOPE items assessing Symptom Impact, and Patient Desired Tolerance Level for Symptoms or Patient Preferences for Symptom Management were used to calculate this measure. The candidate measure Reduction in Pain Severity reports the percentage of patients who had a reduction in reported pain severity. The primary HOPE items used to calculate this measure include Pain Screening, Pain Active Problem, and Patient Desired Tolerance Level for Symptoms or Patient Preferences for Symptom Management. The last candidate measure discussed by the TEP was Timely Reduction of Symptoms which measures the percentage of patients who experience a reduction in the impact of symptoms other than pain. HOPE items assessing Symptom Impact, and Patient Desired Tolerance Level for Symptoms or Patient Preferences for Symptom Management were used to calculate this measure. HOPE items for all three measure are collected at multiple time points across a patient's stay, including at Admission, Symptom Reassessment, Level of Care Change, and Recertification. Overall, the TEP supported each candidate measure and agreed that they were viable for distinguishing hospice quality. We continue to develop all three candidate quality measures.

We are interested in exploring patient preferences for symptom management, addressing patient spiritual and psychosocial needs, and medication management in outcomes of care in development of quality measures. We sought public comment on methods, instruments, or brief summaries on hospice quality initiatives related to goal attainment, patient preferences, spiritual needs, psychosocial needs, and medication management.

Information about the TEP feedback on these quality measures concepts and future measure concepts can be obtained via: *https://www.cms.gov/files/document/2020-hqrp-tep-summary-report.pdf.* Related to the outcome measures and in order to have HOPE pain and symptom measures in the program as soon as possible, we plan to develop process measures, including on pain and symptom management. These process measures may support or complement the outcome measures. We solicit comments on current HOPE-based quality measure development and recommendations for future process and outcome measure constructs.

In the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38484) and as discussed later in this section of the preamble, we are interested in claims-based quality measures in order to leverage the multiple data sources currently available to support quality measure development. Specifically, we intend to develop additional claims-based measures that may enable beneficiaries and their family caregivers to make more informed choices about hospice care and to hold hospices more accountable for the care they provide. As discussed in this section, the HVLDL and HCI claims-based measures support the Meaningful Measures initiative and address gaps in HQRP. Additional claim-based measure concepts we are considering for development include hospice services on weekends, transitions after hospice live discharge, Medicare expenditures per beneficiary (including the share of non-hospice spending during hospice election, and the share for hospice care prior to the last year of life), and post-mortem visits as measures of hospice quality. We intend to submit additional claims-based measures for future consideration and solicit public comment.

We solicited public comment on the aforementioned HOPE- and claims-based quality measures to distinguish between high- and low-quality hospices, support healthcare providers in quality improvement efforts, and provide support to hospice consumers in helping to select a hospice provider. We also solicited public comment on how the candidate measures may achieve those goals.

We are also considering developing hybrid quality measures that would be calculated using claims, assessment (HOPE), or other data sources. Hybrid quality measures allow for a more comprehensive set of information about care processes and outcomes than cannot be calculated using claims data alone. Assessment data can be used to support risk-adjustment. We sought public comment on quality measure concepts and considerations for developing hybrid measures based on a combination of data sources.

We received many comments on future quality measure development aspects. A summary of these comment and our responses to those comments appear below:

Comment: We received several comments suggesting concepts for future quality measures in the HQRP such as measures related to postmortem service, plan of care goal achievement, spiritual care, psychosocial care, veteran services, volunteer activities, visit activity at the time of admission, change of level of care, change of physical location, safety culture, and workforce engagement, and patient and family care needs. Comments urge CMS to monitor duplication of measures when HOPE-based and other future measures are under development. Many commenters emphasized the need to engage providers to share information and for CMS to seek feedback when developing quality measures.

We received many comments expressing the need for HCPCS codes for all hospice disciplines, including spiritual care professionals. These comments also suggested including these disciplines in future claims-based measures to recognize the multi-disciplinary nature of hospice care.

Many commenters noted their concern about the distinction between performance measures and quality of care measures. Commenters emphasized that performance measures should be used to measure program integrity, but should not be publicly reported. Several commenters encouraged CMS to use quality claims-based data and other data sources for hybrid measure, consider the implications of claims-based measures to measure quality, use of survey data if feasible, explore outcome measures related to pain and other symptom management, and explore goal achievement. Several comments suggest CMS explore statewide or regional approaches to measure quality rather than using national analysis and perform rigorous data validation by hospice providers for claims-based measures.

Response: We thank all the commenters for their thoughtful suggestions and feedback related to future of quality measure development for the HQRP. We appreciate suggestions for new quality measures, as well as comments about the public reporting of quality measures. CMS will take these comments under advisement for future consideration of quality measures and the Meaningful Measures System Blueprint. We encourage all key stakeholders to continue to stay informed and engaged through the HQRP Forums, Open Door Forums, Quarterly Updates, and listserv notifications.

8. CAHPS Hospice Survey Participation Requirements for the FY 2023 APU and Subsequent Years

a. Background and Description of the CAHPS Hospice Survey

The CAHPS Hospice Survey is a component of the CMS HQRP which is used to collect data on the experiences of hospice patients and the primary caregivers listed in their hospice records. Readers who want more information about the development of the survey, originally called the Hospice Experience of Care Survey, may refer to 79 FR 50452 and 78 FR 48261. National implementation of the CAHPS Hospice Survey commenced January 1, 2015 as stated in the FY 2015 Hospice Wage Index and Payment Rate Update final rule (79 FR 50452).

b. Overview of the ''CAHPS Hospice Survey Measures''

The CAHPS Hospice Survey measures was re-endorsed by NQF on November 20, 2020. The re-endorsement can be found on the NQF website at: *https://www.qualityforum.org/Measures_Reports_Tools.aspx.* Use the QPS tool and search for NQF number 2651. The survey received its initial NQF endorsement on October 26, 2016 (NQF #2651). We adopted 8 survey based measures for the CY 2018 data collection period and for subsequent years. These eight measures are publicly reported on a designated CMS website, Care Compare, *https://www.medicare.gov/care-compare/.*

c. Data Sources

We previously finalized the participation requirements for the CAHPS Hospice Survey, (84 FR 38484). We propose no changes to these requirements going forward.

d. Public Reporting of CAHPS Hospice Survey Results

We began public reporting of the results of the CAHPS Hospice Survey on Hospice Compare as of February 2018. Prior to the COVID–19 PHE, we reported the most recent 8 quarters of data on the basis of a rolling average, with the most recent quarter of data being added and the oldest quarter of data removed from the averages for each data refresh. Given the exemptions provided due to COVID–19 PHE in the March 27, 2020 Guidance Memorandum,[45] public reporting will continue to be the most recent 8 quarters of data, excluding the exempted quarters; Quarter 1 and Quarter 2 of CY 2020. More information about this is detailed in the section entitled: Proposal for Public Reporting CAHPS-based measures with Fewer than Standard Numbers of Quarters Due to the COVID–19 PHE Exemptions

e. Volume-Based Exemption for CAHPS Hospice Survey Data Collection and Reporting Requirements

We previously finalized a volume-based exemption for CAHPS Hospice Survey Data Collection and Reporting requirements for FY 2021 and every year thereafter (84 FR 38526).

We propose no changes to this exemption. The exemption request form is available on the official CAHPS Hospice Survey website: *http://www.hospiceCAHPSsurvey.org.* Hospices that intend to claim the size exemption are required to submit to CMS their completed exemption request form by December 31, of the data collection year.

Hospices that served a total of fewer than 50 survey-eligible decedent/caregiver pairs in the year prior to the data collection year are eligible to apply for the size exemption. Hospices may apply for a size exemption by submitting the size exemption request form. The size exemption is only valid for the year on the size exemption request form. If the hospice remains eligible for the size exemption, the hospice must complete the size exemption request form for every applicable FY APU period, as shown in table 9.

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TABLE 9: Size Exemption Key Dates FY 2022 Through FY 2026

Fiscal year	Data collection year	Reference year	Size exemption form submission deadline
FY 2022	CY 2020	CY 2019	December 31, 2020
FY 2023	CY 2021	CY 2020	December 31, 2021
FY 2024	CY 2022	CY 2021	December 31, 2022
FY 2025	CY 2023	CY 2022	December 31, 2023
FY 2026	CY 2024	CY 2023	December 31, 2024

f. Newness Exemption for CAHPS Hospice Survey Data Collection and Public Reporting Requirements

We previously finalized a one-time newness exemption for hospices that meet the criteria as stated in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52181). In the FY 2019 Hospice Wage Index and Payment Rate Update final rule (83 FR 38642), we continued the newness exemption for FY 2023, and all subsequent years. We encourage hospices to keep the letter they receive providing them with their CMS Certification Number (CCN). The letter can be used to show when you received your number.

g. Survey Participation Requirements

We previously finalized survey participation requirements for FY 2022 through FY 2025 as stated in the FY 2018 and FY 2019 Hospice Wage Index and Payment Rate Update final rules (82 FR 36670 and 83 FR 38642 through 38643). We also continued those requirements in all subsequent years (84 FR 38526). Table 10 restates the data submission dates for FY 2023 through FY 2025.

[45] *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

TABLE 10: CAHPS Hospice Survey Data Submission Dates for the APU in FY 2023, FY 2024, and FY 2025

Sample months (month of death)*	CAHPS Quarterly Data Submission Deadlines**
FY 2023 APU	
CY January-March 2021 (Quarter 1)	August 11, 2021
CY April-June 2021 (Quarter 2)	November 10, 2021
CY July-September 2021 (Quarter 3)	February 9, 2022
CY October-December 2021 (Quarter 4)	May 11, 2022
FY 2024 APU	
CY January-March 2022 (Quarter 1)	August 10, 2022
CY April-June 2022 (Quarter 2)	November 9, 2022
CY July-September 2022 (Quarter 3)	February 8, 2023
CY October-December 2022 (Quarter 4)	May 10, 2023
FY 2025 APU	
CY January-March 2023 (Quarter 1)	August 9, 2023
CY April-June 2023 (Quarter 2)	November 8, 2023
CY July-September 2023 (Quarter 3)	February 14, 2024
CY October-December 2023 (Quarter 4)	May 8, 2024

* Data collection for each sample month initiates 2 months following the month of patient death (for example, in April for deaths occurring in January).
** Data submission deadlines are the second Wednesday of the submission months, which are the months August, November, February, and May.

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For further information about the CAHPS Hospice Survey, we encourage hospices and other entities to visit: *https://www.hospiceCAHPSsurvey.org.* For direct questions, contact the CAHPS Hospice Survey Team at *hospiceCAHPSsurvey@HCQIS.org* or call 1-(844) 472–4621.

h. Proposal to Add CAHPS Hospice Survey Star Ratings to Public Reporting

CMS currently publishes CAHPS star ratings for several of its public reporting programs including Home Health CAHPS and Hospital CAHPS. The intention in doing so is to provide a simple, easy to understand, method for summarizing CAHPS scores. Star ratings benefit the public in that they can be easier for some to understand than absolute measure scores, and they make comparisons between hospices more straightforward. The public's familiarity with a 1 through 5 star rating system, given its use by other programs, is also a benefit to using this system.

In the proposed rule, we proposed to introduce Star Ratings for public reporting of CAHPS Hospice Survey results on the Care Compare or successor websites no sooner than FY 2022. We proposed that the calculation and display of the CAHPS Hospice Survey Star Ratings be similar to that of other CAHPS Star Ratings programs such as Hospital CAHPS and Home Health CAHPS. The stars would range from one star (worst) to five stars (best). We proposed that the stars be calculated based on ''top-box'' scores for each of the eight CAHPS Hospice Survey measures. Specifically, individual-level responses to survey items would be scored such that the most favorable response is scored as 100 and all other responses are scored as 0. A hospice-level score for a given survey item would then be calculated as the average of the individual-level responses, with adjustment for differences in case mix and mode of survey administration. For a measure composed of multiple items, the hospice-level measure score would be the average of the hospice-level scores for each item within the measure. Similar to other CAHPS programs, we proposed that the cut-points used to determine the stars be constructed using statistical clustering procedures that minimize the score differences within a star category and maximize the differences across star categories.

We proposed to use a two-stage approach to calculate these cut-points. In the first stage, we would determine initial cut-points by calculating the clustering algorithm among hospices with 30 or more completed surveys over 2 quarters (that is, 6 months); restricting these calculations to hospices that meet a minimum sample size promotes stability of cut-points. Depending on whether hospices that meet this minimum sample size have different score patterns than smaller hospices, the initial cut-points may be too high or too low. To ensure that cut-points reflect the full distribution of measure performance, in the second stage, we proposed to compare mean measure scores for the bigger hospices used in the first stage to all other hospices, and update cut-points by adjusting the initial cut-points to reflect the normalized difference between bigger and smaller hospices. This two-stage approach allows for calculation of stable cut-points that reflect the full range of hospice performance. We proposed that hospice star ratings for each measure be assigned based on where the hospice-level measure score falls within these cut-points.

We further proposed to calculate a summary or overall CAHPS Hospice Survey Star Rating by averaging the Star Ratings across the 8 measures, with a weight of ½ for Rating of the Hospice, a weight of ½ for Willingness to Recommend the Hospice, and a weight of 1 for each of the other measures, and then rounding to a whole number. We proposed that only the overall Star Rating be publicly reported and that hospices must have a minimum of 75 completed surveys in order to be assigned a Star Rating. Finally, we proposed to publish the details of the Star Ratings methodology on the CAHPS Hospice Survey website, *www.hospicecahpssurvey.org.* CMS requires no additional resources to create and display CAHPS star ratings.

We solicited comments on these proposals for CAHPS Star Ratings and the public reporting of star ratings no sooner than FY 2022.

Comment: Many commenters expressed concern about the timeframe for implementing CAHPS Hospice Survey star ratings. They suggested that the display of star ratings be delayed because CMS needs to provide additional opportunities for providers to learn about and comment on the details of the methodology. In addition, some commenters wanted CMS to consider creating a single star rating based on both CAHPS and other measures, such as the HOPE tool.

Response: As stated in the proposed rule, we will display CAHPS Hospice Survey star ratings no sooner than FY 2022. Prior to finalizing a timeline, CMS will provide multiple opportunities to share information and receive comments from stakeholders. This could include a special open door forum or other venues for interaction. CMS proposed a CAHPS-only star rating since other portions of Care Compare also display a CAHPS-only star rating (for example, Hospital CAHPS and Home Health CAHPS). We will take the recommendation of a single star rating into consideration for the future.

Comment: A few commenters requested specifically for an explanation for using top-box scoring of individual level responses for the star ratings. They note that other star ratings use a 0–100 linear-scaled score.

Response: CMS analyzed existing data to inform the development of star ratings in the hospice setting. We examined star ratings using linear means and, separately, top-box scores. For CAHPS Hospice Survey data, using top-box scores resulted in wider star rating categories that make the star ratings less sensitive to small changes in scores. For this reason, we proposed to calculate CAHPS Hospice star ratings using top-box scores.

Comment: Several commenters raised a concern regarding whether relatively high levels and tight distribution of performance on CAHPS Hospice Survey measures will result in hospices with high scores receiving 3 or fewer stars. Some commenters were concerned about the comparative nature of CAHPS star ratings and a few called for an alternative methodology that would rate hospices against a benchmark.

Response: Our analyses of existing CAHPS Hospice Survey data demonstrate that hospices with high scores would overwhelmingly receive 4 and 5 stars. Clustering methodology assigns cut points by minimizing differences within star categories and maximizing differences across star categories. This methodology does not force a set number of hospices into each star category. Using a benchmark rather than the clustering approach represents a major shift from our current practice. The current methodology has been successful for other provider types. We do not believe it is necessary to drastically change our methodology for the CAHPS Hospice Survey.

Comment: Some commenters raised questions about using 75 completed surveys as the threshold for public reporting of stars. They were concerned that this number is nearly double the number of survey responses required from home health agencies (40 completes) and more than double the number of responses a hospice must currently have for CAHPS® Hospice Survey measures to be reported (30 completes). They requested a justification for using this number. One commenter stated that given the survey response rate, a hospice would have more than 200 completed surveys in order for star ratings to be displayed. This was a concern for many commenters because it would mean that star ratings would be available only for large hospices. Some commenters suggested that CMS formulate a methodology that would include smaller hospices in star ratings. Additionally, several commenters noted that the proposed rule does not state how many hospices will meet the 75 completes threshold.

Response: CMS seeks to balance the goal of reporting star ratings for as many hospices as possible with the need to ensure that the star ratings can be stably estimated and distinguish between hospices' performance. If a hospice does not have enough survey completes to reliably measure performance, the star ratings would be picking up more noise than true performance. Our analyses have determined that the optimal balance between these two goals is at 75 completed surveys per hospice. We expect that approximately 70 percent of hospices with publicly reported CAHPS Hospice Survey measure scores meet the threshold of 75 completed surveys.

Comment: Several commenters expressed concerns that the public will not interpret the star ratings correctly. They also called for more explanatory information on the Care Compare website.

Response: The star rating approach proposed for CAHPS Hospice Survey measures is similar to what has been used for Medicare Advantage and Part D plan measures and Hospital CAHPS measures successfully for many years. These other settings utilize a clustering algorithm such that providers within a cluster are more alike than providers across clusters. The proposed CAHPS Hospice Survey stars will adopt a similar overall approach, although using top-box scores rather than linear means, based on our analyses of existing data. Consumers have generally welcomed star ratings. We will make explanatory information available to consumers, while recognizing that keeping the interface as streamlined as possible improves the usability of the site for consumers.

Comment: Several commenters stated concerns that the public might misinterpret the lack of star ratings for smaller hospices as being evidence of poor quality care. They called for customer research on how the public would interpret the absence of star ratings as well as research on the extent to which the public understands how star ratings are calculated.

Response: Star Ratings are easy for consumers to understand and interpret and are used in a variety of settings. We will explore alternatives for presenting additional information about star ratings on the Care Compare website so that consumers may be informed about why smaller hospices may not have stars.

Comment: A few commenters requested more details about if and how we will include patient-mix adjustment.

Response: Star ratings are based on CAHPS Hospice Survey measure scores, which are adjusted for case mix and mode of survey administration. Detailed information regarding adjustment of measure scores is available at *https://hospicecahpssurvey.org/en/scoring-and-analysis/.*

Comment: Several commenters raised issues about the eight quarters of data included in public reporting. They believe that this is too long and that it makes it difficult for hospices to use publicly-reported data for quality improvement.

Response: CMS seeks to balance the goal of publicly reporting measure scores for as many hospices as possible with the need to ensure that measure scores can be stably estimated and distinguish between hospices' performance. Rolling up eight quarters of data instead of four ensures that measure scores are available for many more hospices, which improves the usefulness of the Compare web tools for hospice consumers. The eight quarter approach does not result in a delay of when data become available (since the most recent quarters of data are included in the rolled-up score), but it does ensure more accurate measurement. The decision to use eight quarters of rolling data for hospices reflects the size of hospices, which differ in size and other dimensions from other types of entities, such as hospitals and Medicare Advantage contracts, for

which CMS publicly reports scores and star ratings. We note that hospices should be able to receive timely reports and data directly from their survey vendors. We encourage hospices who want to use CAHPS data for quality improvement to talk to their vendors about the reports and data that may be available shortly after data collection.

Comment: A commenter stated that the preview report timeframe is too short and that hospices should receive preview data at least 1 year prior to its publication in order to analyze performance and implement quality improvement.

Response: As stated previously, we recommend that hospices use data from their vendors for quality improvement, rather than wait for publicly-reported data. If we were to provide preview data a year in advance, the publicly reported data would be too old to be a meaningful reflection of the hospice's performance. We believe additional delays in public reporting of data is not in the interest of the public using Care Compare.

Comment: Many commenters expressed concern about publicly reporting data that was collected and/or delivered during the COVID–19 PHE. They commented that these data could be skewed by the public health emergency.

Response: We will not include data from Q1 and Q2 2020 in Star Rating calculations, as hospices were exempted from submitting these quarters of data to CMS due to the COVID–19 PHE.

Comment: Several commenters stated that the CAHPS Hospice Survey is unlike other CAHPS surveys in that the respondents are family members or friends of the deceased—not the patients themselves. They believe this is a key difference between the hospice survey and other CAHPS surveys and called for more information on the Care Compare site to make sure consumers are not misled.

Response: Although Care Compare already notes that for Hospice CAHPS the user is comparing ''. . . hospices based on results from a national survey that asks a family member or friend of a hospice patient about their hospice care experience,'' we will consider whether there are additional ways to highlight this.

Comment: Some commenters objected to the comparative nature of the CAHPS Hospice Survey star ratings, preferring instead, a rating based upon an external criteria rather than one that compares hospices to each other. As a few commenters noted, ''Each hospice is afforded the opportunity to achieve excellent ratings on the CAHPS Hospice Survey. Similarly, this same right should be afforded hospices under the Star Rating system through a clear portrayal Star Rating of performance to consumers and the public that reflects how most respondents scored the hospice, not how the hospice fares compared to all other hospices.'' One commenter also suggested that star ratings calculations be made available to hospices before they are publicly reported.

Response: Similar to other CMS CAHPS star ratings, we propose that the cut-points used to determine CAHPS Hospice Survey stars be constructed using statistical clustering procedures that minimize the score differences within a star category and maximize the differences across star categories. This ensures that star assignments clearly differentiate performance across groups of hospices. Such comparative star ratings, as proposed by CMS, help consumers identify high and low performing hospices. With respect to making calculations available before they are publicly reported, we do plan to provide star ratings calculations in preview reports prior to their display.

Comment: Several commenters noted that CMS is currently conducting a pilot test of a revised CAHPS Hospice Survey questionnaire and wondered whether the release of a new questionnaire would coincide with the introduction of star ratings. They also questioned whether CMS expected that use of a revised questionnaire would increase the number of hospices that achieve 75 completed questionnaires and would, therefore, be included in star ratings.

Response: We are currently conducting an experiment to test a new version of the survey, including the web mode of administration which may have an impact on response rates and the number of survey completes. Results of this experiment will help to inform changes to the survey in the future. We anticipate that star ratings will be released prior to a new version of the survey. Star ratings will continue to be calculated and released as we phase in the new survey version.

Comment: Many commenters questioned the weighting of the components of the star ratings, particularly the decision to weigh the two global questions (Overall Rating and Willingness to Recommend) at 50 percent of the weight for each composite measure.

Response: The Willingness to Recommend and Overall Rating measures are highly correlated with one another, as both provide global assessments of hospice care. Given this, weighting each of the two measures at 100 percent would over-emphasize global assessments of care relative to the other aspects of care assessed by CAHPS Hospice Survey measures. CMS maintains its proposal to weight Willingness to Recommend and Overall Rating at 50 percent each for the purpose of calculating an overall CAHPS Hospice Survey star rating. This approach parallels the one used by CMS for calculating star ratings for hospitals.

Comment: A few commenters questioned whether it is CMS's intent for the CAHPS® to be the sole star rating vehicle for hospice care or whether there would be another star rating for HOPE measures when it is implemented?

Response: The FY 2022 proposal contemplated a CAHPS-only measure in the short-term. At this time, it is premature to determine whether the HOPE tool should be used to create star ratings, either separately from CAHPS or in combination with CAHPS. The HOPE tool is now under development. We will consider other star ratings as applicable.

Comment: One commenter recommended that CMS award star ratings in FY 2022, but suppress public reporting in Care Compare until the August 2023 refresh when all the data will be after the COVID-exempted quarters.

Response: As mentioned previously, we plan to display stars no sooner than FY 2022. We will take into consideration the option of starting the stars display when all data will be after the COVID-exempted quarters.

Comment: One commenter strongly suggested that there should be a ''not applicable'' response option available for each question in the questionnaire. Indeed, they noted that ''Questions such as ''How often did your family member get the help he or she needed for trouble breathing'' or ''How often did your family member get the help he or she needed for constipation'' are difficult for family members to answer if their loved one did not experience issues with those symptoms.''

Response: On the questionnaire, the respondent is asked if their family member experienced the symptom. If they did not experience the symptom, the instructions say to skip to another question. Under these circumstances a ''not applicable'' is not needed.

Comment: A few commenters stated that the survey is too long. One commenter suggested that we should identify the key 1 or 2 questions in each survey domain and use them instead.

Response: We are currently conducting an experiment to test a shorter version of the CAHPS Hospice Survey. Results of this experiment will

help to inform changes to the survey in the future.

Final Decision: After consideration of the public comments, we are finalizing our proposal to display Hospice CAHPS Star ratings no sooner than FY 2022. We plan to provide opportunities for interaction with stakeholders to discuss our plans and methodology and to receive feedback prior to the start of star ratings display. We will also explore the feasibility of conducting a dry run of the star ratings with reporting to hospices via preview reports, which would occur prior to the start of the public display of the ratings.

9. Form, Manner, and Timing of Quality Data Submission

a. Statutory Penalty for Failure To Report

Section 1814(i)(5)(C) of the Act requires that each hospice submit data to the Secretary on quality measures specified by the Secretary. Such data must be submitted in a form and manner, and at a time specified by the Secretary. Section 1814(i)(5)(A)(i) of the Act was amended by the CAA 2021 and the payment reduction for failing to meet hospice quality reporting requirements is increased from 2 percent to 4 percent beginning with FY 2024. The Act requires that, beginning with FY 2014 through FY 2023, the Secretary shall reduce the market basket update by 2 percentage points and then beginning in FY 2024 and for each subsequent year, the Secretary shall reduce the market basket update by 4 percentage points for any hospice that does not comply with the quality data submission requirements for that FY. We received a few comments on this policy. A summary of these comment and our responses to those comments appear below:

Comment: We received several comments objecting to the increase in the percentage penalty for failure to provide quality reporting data.

Response: We thank the commenters for their views, but as noted, this provision is required by section 407(b) of the CAA and does not permit any discretion on the part of the Secretary to implement it.

Comment: Several commenters requested that CMS communicate widely and display prominently notices and information about the increase in the penalty for failure to comply with HQRP requirements. They suggested using multiple avenues of communication including the HQRP website and MLN Connects.

Response: We agree that communicating widely is critically important, to ensure as many hospices as possible are aware not only of the increase in penalty, but also clearly understand the HQRP reporting requirements and the APU process. We will consider using multiple avenues for communication, including this rule, the Medicare Claims Manual, the HQRP website, such as the HQRP Requirements and Best Practices web page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HQRP-Requirements-and-Best-Practices* and the Training and Education Library page at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Quality-Reporting-Training-Training-and-Education-Library.* We will also consider opportunities to communicate through webinars, Open Door Forums, and other resources as relevant.

Comment: A few commenters did not agree with the CAA 2021 provision that removes the prohibition on public disclosure of hospice surveys performed by a national accreditation agency in section 1865(b) of the Act, thus allowing the Secretary to disclose such accreditation surveys. Many commenters also noted the special focused program that requires each state and local survey agency, and each national accreditation body with an approved hospice accreditation program, to submit information respecting any survey or certification made with respect to a hospice program.

Response: The proposed regulatory policies to implement the hospice survey and enforcement provisions in section 407 of CAA, 2021 were included in CY 2022 Home Health Prospective Payment System proposed rule with the comment period found here: *https://www.govinfo.gov/content/pkg/FR-2021-07-07/pdf/2021-13763.pdf.* We encourage commenters to provide us input and comments on these provisions in response to that rule. The link to the **Federal Register** can be found here: *CMS–1747–P CY 2022 Home Health Prospective Payment System Rate Update.* Note: The comment period closes on August 27, 2021.

b. Compliance

HQRP Compliance requires understanding three timeframes for both HIS and CAHPS. (1) The relevant Reporting Year, payment FY and the Reference Year. The ''Reporting Year'' (HIS)/''Data Collection Year'' (CAHPS). This timeframe is based on the CY. It is the same CY for both HIS and CAHPS. If the CAHPS Data Collection year is CY 2022, then the HIS reporting year is also CY 2022. (2) The APU is subsequently applied to FY payments based on compliance in the corresponding Reporting Year/Data Collection Year. (3) For the CAHPS Hospice Survey, the Reference Year is the CY prior to the Data Collection Year. The Reference Year applies to hospices submitting a size exemption from the CAHPS survey (there is no similar exemption for HIS). For example, for the CY 2022 data collection year, the Reference Year, is CY 2021. This means providers seeking a size exemption for CAHPS in CY 2022 would base it on their hospice size in CY 2021. Submission requirements are codified in § 418.312.

For every CY, all Medicare-certified hospices are required to submit HIS and CAHPS data according to the requirements in § 418.312. Table 11 summarizes the three timeframes. It illustrates how the CY interacts with the FY payments, covering the CY 2020 through CY 2023 data collection periods and the corresponding APU application from FY 2022 through FY 2025.

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TABLE 11: HQRP Reporting Requirements and Corresponding Annual Payment Updates

Reporting Year for HIS and Data Collection Year for CAHPS data (Calendar year)	Annual Payment Update Impacts Payments for the FY	Reference Year for CAHPS Size Exemption (CAHPS only)
CY 2020	FY 2022 APU	CY 2019
CY 2021	FY 2023 APU	CY 2020
CY 2022	FY 2024 APU*	CY 2021
CY 2023	FY 2025 APU	CY 2022

* Beginning in FY 2024 and all subsequent years, the payment penalty is 4 percent. Prior to FY 2024, the payment penalty is 2 percent.

As illustrated in Table 11, CY 2020 data submissions compliance impacts the FY 2022 APU. CY 2021 data submissions compliance impacts the FY 2023 APU. CY 2022 data submissions compliance impacts FY 2024 APU. This CY data submission impacting FY APU pattern follows for subsequent years.

c. Submission Data and Requirements

As finalized in the FY 2016 Hospice Wage Index and Payment Rate Update final rule (80 FR 47192), hospices' compliance with HIS requirements beginning with the FY 2020 APU determination (that is, based on HIS-Admission and Discharge records submitted in CY 2018) are based on a timeliness threshold of 90 percent. This means CMS requires that hospices submit 90 percent of all required HIS records within 30-days of the event (that is, patient's admission or discharge). The 90-percent threshold is hereafter referred to as the timeliness compliance threshold. Ninety percent of all required HIS records must be submitted and accepted within the 30-day submission deadline to avoid the statutorily-mandated payment penalty.

To comply with CMS' quality reporting requirements for CAHPS, hospices are required to collect data monthly using the CAHPS Hospice Survey. Hospices comply by utilizing a CMS-approved third-party vendor. Approved Hospice CAHPS vendors must successfully submit data on the hospice's behalf to the CAHPS Hospice Survey Data Center. A list of the approved vendors can be found on the CAHPS Hospice Survey website: *www.hospicecahpssurvey.org.* Table 12. HQRP Compliance Checklist illustrates the APU and timeliness threshold requirements.

TABLE 12: HQRP Compliance Checklist

Annual Payment Update	HIS	CAHPS
FY 2022	Submit at least 90 percent of all HIS records within 30 days of the event date (patient's admission or discharge) for patient admissions/discharges occurring 1/1/20 – 12/31/20.	Ongoing monthly participation in the Hospice CAHPS survey 1/1/2020 – 12/31/2020
FY 2023	Submit at least 90 percent of all HIS records within 30 days of the event date (patient's admission or discharge) for patient admissions/discharges occurring 1/1/21 – 12/31/21.	Ongoing monthly participation in the Hospice CAHPS survey 1/1/2021 – 12/31/2021
FY 2024	Submit at least 90 percent of all HIS records within 30 days of the event date (patient's admission or discharge) for patient admissions/discharges occurring 1/1/22 – 12/31/22.	Ongoing monthly participation in the Hospice CAHPS survey 1/1/2022 – 12/31/2022

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Most hospices that fail to meet HQRP requirements do so because they miss the 90 percent threshold. We offer many training and education opportunities through our website, which are available 24/7, 365 days per year, to enable hospice staff to learn at the pace and time of their choice. We want hospices to be successful with meeting the HQRP requirements. We encourage hospices to use this website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Quality-Reporting-Training-Training-and-Education-Library.*

For more information about HQRP Requirements, please visit the frequently-updated HQRP website and especially the Best Practice, Education and Training Library, and Help Desk web pages at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-*

Quality-Reporting. We also encourage members of the public to go to the HQRP web page and sign-up for the Hospice Quality ListServ to stay informed about HQRP.

d. Update on Transition to iQIES

In the FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38484), we finalized the proposal to migrate our systems for submitting and processing assessment data. Hospices are currently required to submit HIS data to CMS using the Quality Improvement and Evaluation System (QIES) Assessment and the Submission Processing (ASAP) system. The FY 2020 Hospice Wage Index and Payment Rate Update final rule (84 FR 38484) finalized the proposal to migrate to a new internet Quality Improvement and Evaluation System (iQIES) that will enable us to make real-time upgrades. We are designating that system as the data submission system for the Hospice QRP. We will notify the public about any system migration updates using subregulatory mechanisms such as web page postings, listserv messaging, and webinars.

We received several on the transition to iQIES. A summary of these comment and our responses to those comment appear below:

Comment: Several commenters requested 6-month minimum notice prior to the transition of hospice to the iQIES system. Some of these commenters further requested that CMS provide announcements about the upcoming implementation of hospice in iQIES through all CMS and MAC communication platforms to ensure wide penetration of the message, and ensure a smooth transition given lessons from the transition of other settings to iQIES.

Response: We appreciate that providers will benefit from advanced notice regarding the transition of hospice to the iQIES systems. We plan to communicate with the provider community via sub-regulatory means about the upcoming transition as the timing becomes clear, and will provide sufficient time and appropriate information for a smooth transition.

10. Public Display of ''Quality Measures'' and Other Hospice Data for the HQRP

a. Background

Under section 1814(i)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by hospices available to the public. These procedures shall ensure that individual hospices have the opportunity to review their data prior to these data being made public on our designated public website. To meet the Act's requirement for making quality measure data public, we launched Hospice Compare in August 2017. This website allows consumers, providers, and other stakeholders to search for all Medicare-certified hospice providers and view their information and quality measure scores. In September 2020, CMS transitioned Hospice Compare to the Care Compare website. Hospice Compare was discontinued in December 2020. Care Compare supports all Medicare settings and fulfills the Act's requirements for the HQRP. For more information about Care Compare, please see the Update on the Hospice Quality Reporting Requirements for FY 2022 in section D.

Since 2017, we have increased and improved available information about the care hospices provide for consumers. To indicate the quality of care hospices provide, we first posted the seven HIS Measures (NQF #1641, NQF #1647, NQF #1634, NQF #1637, NQF #1639, NQF #1638, and NQF #1617) in 2017, and then added the CAHPS Hospice Survey measure (NQF #2651) and the HIS Comprehensive Assessment at Admission (NQF #3235) in 2018. In 2019, we added the Hospice Visits When Death is Imminent (Measure 1) to the website.

As discussed previously, we are finalizing our proposal to remove the seven HIS Measures from public reporting on Care Compare no earlier than May 2022. The Hospice Item Set V3.00 PRA Submission replaced the HVWDII measure with a more robust version: The claims-based measure HVLDL. We will publicly report the HVLDL no earlier than May 2022. We are also finalizing our proposal to publicly report the HCI, another claims-based measure no earlier than May 2022. In addition to the publicly-reported quality measure data, in 2019 we added to public reporting, information about the hospices' characteristics, taking raw data available from the Medicare Public Use File and other publicly-available government data sources and making them more consumer friendly and accessible for people seeking hospice care for themselves or family members, (83 FR 38649). This publicly reported information currently includes diagnoses, location of care, and levels of care provided.

b. Data Collection and Reporting During a Public Health Emergency

(1). Background: COVID–19 Public Health Emergency Temporary Exemption and Its Impact on the Public Reporting Schedule

Under authority of section 319 of the Public Health Service (PHS) Act, the Secretary declared a PHE effective as of January 27, 2020. On March 13, 2020, the President declared a national state of emergency under the Stafford Act, effective March 1, 2020, allowing the Secretary to invoke section 1135(b) of the Act (42 U.S.C. 1320b–5) to waive or modify the requirements of titles XVIII, XIX, and XXI of the Act and regulations to the extent necessary to address the COVID–19 PHE. Many waivers and modifications were made effective as of March 1, 2020 [46] [47] in accordance with the president's declaration. On March 27, 2020, we sent a guidance memorandum under the subject title, ''Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19'' [48] to the Medicare Learning Network (MLN) Connects Newsletter and Other Program-Specific Listserv Recipients,[49] hereafter referred to as the March 27, 2020 CMS Guidance Memorandum. In that memo, which applies to HIS and CAHPS Hospice Survey, CMS granted an exemption to the HQRP reporting requirements for Quarter 4 (Q4) 2019 (October 1, 2019 through December 31, 2019), Quarter 1 (Q1) 2020 (January 1,

[46] Azar, A. M. (2020 March 15). *Waiver or Modification of Requirements Under Section 1135 of the Social Security Act.* Public Health Emergency. *https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.*

[47] *https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.*

[48] *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

[49] (2020, March 27). Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19. Centers for Medicare & Medicaid Services. *.https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

2020 through March 30, 2020), and Quarter 2 (Q2) 2020 (April 1, 2020 through June 30, 2020). We discuss the impact to the HIS here, and the impact to the CAHPS Hospice Survey further in section F.10.b.4. For HIS, the quarters are defined based on submission of HIS admission or discharge assessments.

The exemption has impacted the public reporting schedule. Since launching Hospice Compare in 2017, HIS-measures have been reported using 4 quarters of data. The 4 quarters included are the most recent data that have gone through Review and Correct processes, have been issued in a provider preview report, and have time allotted for addressing requests for data suppression before being publicly reported. As discussed in the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52183), CMS requires at least 4 quarters of data to establish the scientific acceptability for our HIS-based quality measures. For CAHPS-based measures, we have reported CAHPS measures using eight rolling quarters of data on Hospice Compare since 2018. In the FY 2017 Hospice Wage Index and Payment Rate Update final rule (81 FR 52143), we stated that we would continue CAHPS reporting with eight rolling quarters on an ongoing basis. This original public reporting schedule included the exempted quarters of Q4 2019 and Q1 and Q2 2020 in six refreshes for HIS and 11 refreshes for CAHPS. Table 13 displays the original schedule for public reporting prior to the COVID–19 PHE.

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TABLE 13: Original Public Reporting Schedule with Refreshes Affected by COVID-19 PHE Exemptions for the HQRP

Quarter Refresh	HIS Quarters in Original Schedule for Care Compare	CAHPS Quarters in Original Schedule for Care Compare
*November 2020	Q1 2019- Q4 2019	Q1 2018-Q4 2019
*February 2021	Q2 2019- Q1 2020	Q2 2018-Q1 2020
*May 2021	Q3 2019-Q2 2020	Q3 2018-Q2 2020
*August 2021	Q4 2019- Q3 2020	Q4 2018-Q3 2020
*November 2021	Q1 2020- Q4 2020	Q1 2019-Q4 2020
*February 2022	Q2 2020-Q1 2021	Q2 2019-Q1 2021
†May 2022	Q3 2020-Q2 2021	Q3 2019-Q2 2021
†August 2022	Q4 2020-Q3 2021	Q4 2019-Q3 2021
†November 2022	Q1 2021-Q4 2021	Q1 2020-Q4 2021
†February 2023	Q2 2021-Q1 2022	Q2 2020-Q1 2022
†May 2023	Q3 2021-Q2 2022	Q3 2020-Q2 2022

*Exemption affects both HIS and CAHPS data for refresh; †Exemption affects only CAHPS data for refresh.

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During the spring and summer of 2020, we conducted testing to inform decisions about publicly reporting data for those refreshes which include exempt data. The testing helped us develop a plan for posting data as early as possible, for as many hospices as possible, and with scientific acceptability similar to standard threshold for public reporting. The following sections provide the results of our testing and explain how we used the results to develop a plan that we believe allows us to achieve these objectives as best as possible.

(2). Update on Use of Q4 2019 Data and Data Freeze for Refreshes in 2021

In the March 27, 2020 Guidance Memorandum, we stated that we should not include any post-acute care (PAC) quality data that are greatly impacted by the exemption in the quality reporting programs. Given the timing of the COVID–19 PHE onset, we determined that we would use any data that was submitted for Q4 2019. We conducted analyses of those data to ensure that their use was appropriate. In the original schedule (Table 13) the November 2020 refresh includes Q4 2019 data for HIS- and CAHPS-based measures (Q1 through Q4 2019 for HIS data and Q1 2018 through Q4 2019 for CAHPS data) and is the last refresh before Q1 2020 data are included. Before proceeding with the November 2020 refresh, we conducted testing to ensure that, even though we made an exception to reporting requirements for Q4 2019 in March 2020, public reporting would still allow us to publicly report data for a similar number of hospice providers, as compared to standard reporting. Specifically, we compared submission rates in Q4 2019 to average annual rates (Q4 2018 through Q3 2019) to assess the

extent to which hospices had taken advantage of the exemption, and thus the extent to which data and measure scores might be affected. We observed that the HIS data submission rate for Q4 2019 was in fact 1.8 percent higher than the previous CY (Q4 2018). For the CAHPS Hospice Survey, 2.1 percent more hospices submitted data in Q4 2019 than in Q4 2018. We note that Q4 2019 ended before the onset of the COVID–19 PHE in the United States (U.S.). Thus, we proceeded with including these data in measure calculations for the November 2020 refresh.

As for Q1 and Q2 2020, we determined that we would not use HIS or CAHPS data from these quarters for public reporting given the timing of the COVID–19 PHE onset. All refreshes, during which we decided to hold these data constant, included more than 2 quarters of data that were affected by the CMS-issued COVID reporting exceptions; thus we did not have an adequate amount of data to reliably calculate and publicly display provider measures scores. Consequently, we determined to freeze the data displayed, that is, holding data constant after the November 2020 refresh without subsequently updating the data through November 2021. This decision was communicated to the public in a Public Reporting Tip Sheet, which is located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HQRP-Requirements-and-Best-Practices.*

(3). Public Reporting of HIS-based Measures With Fewer Than Standard Numbers of Quarters Due to COVID–19 PHE Exemption in February 2022

As noted previously, we used Q4 2019 data for public reporting in November 2020 and froze that data for the February, May, August, and November 2021 refreshes. This addressed five of the six COVID–19 PHE-affected quarters for HIS-based measures, and five of the 11 COVID–19 PHE-affected quarters of CAHPS-based measures.

Because November 2020 refresh data will become increasingly out-of-date and thus less useful for consumers, we analyzed whether it would be possible to use fewer quarters of data for the last refresh affected by the exemption (February 2022) and thus more quickly resume public reporting with updated quality data. Using fewer quarters of more recent data, the first option, would require that (1) a sufficient percentage of providers would still likely have enough assessment data to report quality measures (reportability); and (2) fewer quarters would likely produce similar measure scores for hospices, and thus not unfairly represent the quality of care hospices provide during the period reported in a given refresh (reliability). To assess these criteria, we conducted reportability and reliability analysis using 3 quarters of data in a refresh, instead of the standard 4 quarters of data for reporting HIS-based measures. Specifically, we used historical data to calculate HIS-based quality measures under two scenarios:

- Standard Public Reporting (SPR) Scenario: We used data from the four quarters of CY 2019, which represent CY 2020 public reporting in the absence of the temporary exemption from the submission of PAC quality data, as the basis for comparing simulated alternatives. For HIS-based measures, we used quarters Q1 through Q4 2019.
- COVID–19 PHE Affected Reporting (CAR) Scenario: We calculated quality measures using Q2 2019, Q3 2019, and Q4 2019 data, to simulate using only Q3 2020, Q4 2020, and Q1 2021 data for public reporting.

The HIS Comprehensive Assessment Measure is based on the receipt of care processes at the time of admission. Therefore for the COVID–19 Affected Reporting (CAR) Scenario, we excluded data for patient stays with admission dates in Q1 2019.

For each scenario, we calculated the reportability as the percent of hospices meeting the 20-case minimum for public reporting (the public reporting threshold). To test the reliability of restricting the providers included in the Standard Public Reporting (SPR) Scenario to those included in the CAR Scenario, we performed three tests. First, we evaluated measure correlation using the Pearson and Spearman correlation coefficients, which assess the alignment of hospices' HIS Comprehensive Assessment Measure scores between scenarios. Second, for each scenario, we conducted a split-half reliability analysis and estimated intra-class correlation (ICC) scores, where higher scores imply better internal reliability. Modest differences in ICC scores between scenarios would suggest that using fewer quarters of data does not impact the internal reliability of the results. Third, we estimated reliability scores. A higher value in these scores indicates that HIS Comprehensive Assessment Measure values are relatively consistent for patients admitted to the same hospice and variation in the measure reflects true differences across providers.

Testing results show that the CAR scenario—specifically using 3 quarters of data for the HIS Comprehensive Assessment Measure—demonstrates acceptable levels of reportability and reliability. As displayed in Table 14, the number of providers who met the public reporting threshold for the HIS Comprehensive Assessment Measure decreases by 236 (or by 5.2 percentage points) when reporting three versus four quarters of data. In the FY 2014 Hospice Wage Index and Payment Rate Update final rule (78 FR 48234) we stated that reportability of 71 percent through 90 percent is acceptable. Therefore using 3 quarters of data for the HIS Comprehensive Assessment Measure would achieve acceptable reportability shown in Table 14.

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TABLE 14: Reportability: Percent of Providers Meeting Measure Public Reporting Thresholds

	Reportability		
Measure	**COVID-19 Affected Reporting (CAR) Met Threshold # (%) Providers**	**Standard Public Reporting (SPR) Met threshold # (%) Providers**	**Difference (CAR -SPR)**
HIS Comprehensive Assessment Measure	3,842 (83.9%)	4,078 (89.1%)	-236 (-5.2%)

Table 14 indicates that the reliability of the HIS Comprehensive Assessment Measure scores is similar for the CAR and SPR scenarios. Testing also yielded correlation coefficients above 0.9, indicating a high degree of agreement between hospices' HIS Comprehensive Assessment Measure scores when using 3 or 4 quarters of data. The results also show that th e HIS Comprehensive Assessment Measure's ICC for CAR and SPR scenarios are similar, with only a 0.02 difference. This implies high internal reliability of the measure in both scenarios. The median reliability scores for the HIS Comprehensive Assessment Measure are also very similar in both CAR and SPR scenarios. This indicates that scores estimated using 3 quarters of data continue to capture provider-level differences and that admission-level scores remain consistent within hospices.

TABLE 15: Reliability: Correlations, Split-Half Testing, and Reliability Score for COVID-19 Affected (CAR) and Standard Public Reporting (SPR) Scenarios

	Correlation between CAR and SPR		**Split-Half Reliability Testing**			**Reliability Score**		
Measure	Pearson	Spearman	ICC (CAR)	ICC (SPR)	Difference (CAR - SPR)	Median Score (CAR)	Median Score (SPR)	Difference (CAR - SPR)
HIS Comprehensive Assessment Measure	0.98	0.96	0.95	0.93	0.02	97.5	97.7	-0.2

ICC = Intra-class Coefficient

In Table 15, we explore changes in hospices' relative rankings between the SPR and CAR scenarios. For each scenario, we divided hospices in quintiles based on their HIS Comprehensive Assessment Measure score, such that higher scores are in a higher quintile. Changes in a hospices' quintile from the SPR to CAR scenario would indicate a re-ranking of hospices when using 3 quarters compared to 4 quarters. Over 93 percent of hospices remain in the same quintile, suggesting that the ranking of hospices is fairly stable between the SPR and CAR scenarios.

TABLE 16: Performance: Comparison of Quintile Rankings between COVID-19 PHE Affected (CAR) and Standard Public Reporting (SPR) Scenarios

	Overall			**Rural Providers**			**Urban Providers**		
Measure	% Same Quintile	% CAR Lower Quintile	% CAR Higher Quintile	% Same Quintile	% CAR Lower Quintile	% CAR Higher Quintile	% Same Quintile	% CAR Lower Quintile	% CAR Higher Quintile
HIS Comprehensive Assessment Measure	93.4%	2.4%	4.2%	93.5%	2.1%	4.4%	93.3%	2.5%	4.2%

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We also used the results presented in Table 16 to assess the option of reporting Q4 2019, Q3 2020, Q4 2020, and Q1 2021 for the February 2022 refresh. This option maintains requirements in the FY 2017 Hospice Wage Index and Payment Update final rule for publicly reporting 4 quarters of data, but it requires using some data that are more than 2 years old. Also, the relatively high number of hospices that meet the public reporting threshold in the CAR scenario, relative to the SPR scenario, with just 3 quarters of data justify the use of 3 quarters in the unusual circumstances of the COVID–19 PHE and its associated exemptions.

We are finalizing our proposal that, in the COVID–19 PHE, we would use 3 quarters of HIS data for the final affected refresh, the February 2022 public reporting refresh of Care Compare for the Hospice setting. Using 3 quarters of data for the February 2022 refresh would allow us to begin displaying Q3 2020, Q4 2020, and Q1 2021 data in February 2022, rather than continue displaying November 2020 data (Q1 2019 through Q4 2019). We believe that updating the data in February 2022 by more than a year relative to the November 2020 freeze data would assist consumers by providing more relevant quality data and allow hospices to demonstrate more recent performance. Our testing results indicate we can achieve these positive impacts while maintaining high standards for reportability and reliability. Table 16 summarizes the comparison between the original schedule for public reporting with the revised schedule (that is, frozen data) and with the proposed schedule that is, using 3 quarters in the February 2022 refresh.

We solicited public comment on this proposal to use 3 quarters of HIS data for the February 2022 public reporting refresh. We received many comments this proposal on related questions about publicly reporting claims-based measures using data from the COVID–19 PHE. A summary of the comments received regarding public reporting and our responses those comments appear below.

Comment: We received several comments supporting our proposal to begin public reporting in February 2022 using Q3 and Q4 of 2020 and Q1 of 2021. These commenters also suggested that CMS post a statement that the data displayed include care provided during the COVID–19 PHE on Care Compare until August 2023. One commenter opposed the public reporting of any quality data collected during the COVID–19 PHE (not just the Q1 and Q2 2020 which were subject to the exemptions), because of the impact COVID–19 had on hospice processes and operations.

Response: We appreciate the commenters' support for this proposal. In response to the commenter who did not support this proposal, we would like to emphasize that, while we recognize that the impact of COVID–19 has impacted the hospice community, we also believe that we have a responsibility to consumers to make informed decisions about selecting care. Providing information for decision-making is all the more important during and in the wake of a COVID–19 PHE, when our health as a nation has been shaken.

We disagree with commenters that notices should be posted on Care Compare regarding the inclusion of data from the COVID–19 PHE as such notice would not help consumers distinguish between hospices in their region. Instead, we will continue to post national averages for quality measures, and will add state scores for all measures no earlier than May 2022. This information will help consumers understand relative performance at national and local levels in light of the COVID–19 PHE.

Given the overall positive response to our proposal, we believe that the proposed approach balances fairness to providers with a commitment to transparency and information for consumers.

Comment: Several commenters expressed concern about publicly reporting claims-based measures using data from care provided during the COVID–19 PHE. Specifically, they stated that claims from the COVID–19 PHE would not reflect typical hospice services. Comments specific to HCI noted that abnormalities due to the COVID–19 PHE would affect all of the indicators, while those for HVLDL indicated that the number of in-person visits likely fell during the COVID–19 PHE due to patient and caregiver preferences, with implications for quality measurement. The commenters recommended that CMS post a notice on Care Compare to ensure consumers understand the context, with particular attention to the fact that telehealth visits are not captured in claims reporting.

Response: We appreciate commenters' concerns about publicly reporting claims from the COVID–19 PHE. As stated earlier, we pre-emptively issued the March 27, 2020 CMS Guidance Memorandum making 2019 Q4 and Q1 and Q2 2020 exempt from reporting requirements. In that Memorandum, we stated that we would not include any post acute care (PAC) quality data that are greatly impacted by the exemption in the quality reporting programs. Given the timing of the COVID–19 PHE onset in the U.S., we determined that we would use data that were submitted for Q4 2019. We will apply the principles of this Memorandum to new claims-based measures for hospice. Thus, we will publicly report claims data for care delivered in Q4 2019 and Q3 2020 onward, but we will not publicly report claims data for care delivered Q1 and Q2 of 2020. This approach aligns with what we are doing for the other PAC setting Quality Reporting Programs, including home health (see section III.G).

We acknowledge that the COVID–19 PHE did not end at the beginning of Q3 2020. Our testing indicates that claims data from the COVID–19 PHE are generally stable. Although the number of visits in did visibly decline in 2020, we remain committed to re-initiating publicly reporting of claims data beginning in Q3 2020 for the following reasons: (i) We believe that we have an important commitment to consumers of hospice care to empower them to make informed decisions. This is particularly important during the COVID–19 PHE; (ii) With annual reporting of claims data, we can reasonably state that the COVID–19 PHE affected hospices nationally in a similar way. Given that HCI is scored relative to the national average, scores will be accounted for as part of the measure calculation. To the extent there have been regional differences, we will also provide state scores for both HCI and HVLDL no earlier than May 2022, so that consumers can benchmark to more local realities.

We respectfully disagree with commenters who have requested that we post a notice on Care Compare alerting consumers to potential abnormalities in claims data wholly or partially coming from COVID–19 PHE (excluding Q1 and Q2 2020). Despite the COVID–19 PHE, we would expect that hospices would still provide comprehensive care to hospice patients during the pandemic, and believe that telehealth visits are not full substitutes for care provided in person, particularly in the case of the visits measured in the HVLDL and HCI measures. We acknowledge that there may have been an increase in refusals during the COVID–19 PHE. However, this increase would likely impact hospices in a region similarly, and thus will not impact a hospice's score relative to local competitors. We will include state average scores to further ensure any regional differences in the impact of the

COVID–19 PHE on hospices are captured for consumers. For these reasons, adding disclaimer text as suggested would not help consumers seeking information make decisions about care options.

Final Decision: We are finalizing our proposal to resume public reporting of HIS quality measures in February 2022 using data from Q3 and Q4 of 2020 and Q1 of 2021.

TABLE 17: Original, Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions

Quarter Refresh	HIS Quarters in Original Schedule for Care Compare (number of quarters)	HIS Quarters in revised/proposed Schedule for Care Compare (number of quarters)
November 2020	Q1 2019- Q4 2019 (4)	Q1 2019- Q4 2019 (4)
February 2021	Q2 2019- Q1 2020 (4)	Q1 2019- Q4 2019 (4)
May 2021	Q3 2019-Q2 2020 (4)	Q1 2019- Q4 2019 (4)
August 2021	Q4 2019- Q3 2020 (4)	Q1 2019- Q4 2019 (4)
November 2021	Q1 2020- Q4 2020 (4)	Q1 2019- Q4 2019 (4)
February 2022	Q2 2020-Q1 2021 (4)	Q3 2020-Q1 2021 (3)

Note: The shaded cells represent data frozen (posted and held constant on Care Compare) due to COVID-19 PHE.

(4). Proposal for Public Reporting of ''CAHPS Hospice Survey-based Measures'' Due to COVID–19 PHE Exemption

Prior to COVID–19 PHE, the CAHPS Hospice Survey publicly reported the most recent eight rolling quarters of data. We propose to continue to report the most recent 8 quarters of available data after the freeze, but not to include the data from the exempted quarters of Q1 and Q2 of 2020 as issued in the March 27, 2020 Guidance Memorandum with the effected quarters. The optional data submission for Q4 2019 results in publicly reporting of that data since the CAHPS Hospice Survey from that quarter were not impacted. The data submitted for Q4 2019 referred to deaths that occurred prior to COIVD–19. For the CAHPS Hospice Survey, 2.1 percent more hospices submitted data in Q4 2019 than in the same quarter a year earlier.

Like HIS, our goal is to report as much of the most recent CAHPS Hospice Survey data as possible, to display data for as many hospices as possible, and to maintain the reliability of the data.

Similar to HIS, the CAHPS Hospice Survey reviewed the data for reportability using fewer quarters than normal. However, we found that using fewer than 8 quarters of data would have two important negative impacts on public reporting. First, it would reduce the proportion of hospices that would have CAHPS Hospice Survey data displayed on Care Compare. An analysis of the 8 quarters of data from Q1 2018 through Q4 2019 (publicly reported in November 2020) shows there were 5,041 active hospices. Of these hospices: 2,941 (58.3 percent) had 30+ completes for those 8 quarters, and had scores publicly reported. Fewer hospices, 2,328 (46.2 percent), would have had 30+ completes if 4 quarters of data were used to calculate scores and 1,970 (39.1 percent) would have 30+ completes if 3 quarters were used to calculate scores. In addition, the overall reliability of the CAHPS scores would decline with fewer quarters of data. For these reasons, we determined the best course of action would be to continue to publicly report the most recent 8 quarters of data, but exempting Q1 and Q2 2020. This will allow us to maximize the number of hospices that will have CAHPS scores displayed on Care Compare, protect the reliability of the data, and report as much of the most recent data as possible.

CMS froze CAHPS data starting with the November 2020 refresh and concluding with the November 2021 refresh. We propose that starting with the February 2022 refresh, CMS will display the most recent 8 quarters of CAHPS Hospice Survey data, excluding Q1 and Q2 2020. We will resume public reporting by displaying 3 quarters of post-exemption data, plus five quarters of pre-exemption data. (Please see Table 18.) We propose that in each refresh subsequent to February 2022, we will report one more post-exemption quarter of data and one fewer pre-exemption quarter of data until we reach eight quarters of post-exemption data in May of 2023. We further propose that as of August 2023, we will resume reporting a rolling average of the most recent 8 quarters of data. Table 18 specifies the quarters for each refresh. This will allow us to report the maximum amount of new data, maintain reliability of the data, and permit the maximum number of hospices to receive scores. In addition, Table 18 shows the proposed CAHPS public reporting schedule during and after the data freeze.

TABLE 18: Proposed CAHPS Hospice Survey Public Reporting Quarters During and After the Freeze

Refresh	Publicly Reported Quarters
Freeze:	*Q1 2018-Q4 2019*
*November 2020-November 2021**	
February 2022	Q4 2018 – Q4 2019, Q3 2020 – Q1 2021
May 2022	Q1 2019-Q4 2019, Q3 2020-Q2 2021
August 2022	Q2 2019-Q4 2019, Q3 2020-Q3 2021
November 2022	Q3 2019-Q4 2019, Q3 2020-Q4 2021
February 2023	Q4 2019, Q3 2020-Q1 2022
May 2023	Q3 2020-Q2 2022
*The grey shading refers to the frozen quarters.	

We sought public comment on this proposal to publicly report the most-recently available 8 quarters of CAHPS data starting with the February 2022 refresh and going through the May 2023 refresh on Care Compare because we cannot publicly report Q1 2020 and Q2 2020 data due to the COVID–19 PHE.

Comment: One commenter agreed with our proposal to report the eight most recent quarters of data for the CAHPS Hospice Survey, skipping the exempted quarters. They also requested that Care Compare provide information to users explaining that the published data included pre-COVID quarters. They wanted this continued until all publicly-reported data is from after the exempted quarters.

Response: We thank the commenter and will take this into consideration as information for Care Compare is developed. We will work with colleagues to provide information on Care Compare that alerts users the composition of the data.

Final Decision: We are finalizing our proposal to publicly report the most-recently available 8 quarters of CAHPS data starting with the February 2022 refresh and going through the May 2023 refresh on Care Compare because we cannot publicly report Q1 2020 and Q2 2020 data due to the COVID–19 PHE.

c. Quality Measures To Be Displayed on Care Compare in FY 2022 and Beyond

(1). Removal of the Seven ''Hospice Item Set Process Measures'' From Public Reporting

We are finalizing our proposal to remove the seven HIS process measures from the HQRP as individual measures, and no longer applying them to the FY 2024 APU and thereafter. We are finalizing our proposal to remove the seven HIS process measures no earlier than May 2022 refresh from public reporting on Care Compare and from the Preview Reports but continue to have it publicly available in the data catalogue at *https://data.cms.gov/provider-data/topics/hospice-care.*

We solicited public comment on this proposal to remove the seven HIS process measures from public reporting on Care Compare. We received several comments from various stakeholders. A summary of the comments we received on this proposal and our responses to those comments appear below.

Comment: The majority of commenters supported the removal of the seven HIS process measures no earlier than May 2022. However, a number of comments suggested that CMS continue providing the option for consumers to view detailed information about the individual measures that make up the HIS Comprehensive Assessment measure for transparency. One commenter who opposed the proposal to remove the seven HIS measures expressed concern that such a removal runs counter to the objectives of Care Compare to provide a personalized experience. Some comments expressed concern about the public's ability to be aware of and find the seven HIS measure scores in the Provider Data Catalogue.

Response: CMS does not believe that the public display of the individual process measures on Care Compare will add value for consumers. The individual measures show performance for only one process and do not demonstrate whether the hospice provides high-quality care overall, as an organization. Conversely, the HIS Comprehensive Assessment Measure, which is a single composite measure, differentiates hospices by holding them accountable for completing all seven process measures to ensure these core hospice services are completed for all patients. This interdisciplinary, holistic scope of the HIS Comprehensive Assessment Measure better aligns with the public's expectations for hospice care. We maintain transparency since

stakeholders, who are interested in the seven HIS measures, will have access to the Provider Data Catalogue where they can find all HIS component measure scores.

We respectfully disagree that having the seven HIS measures listed is more transparent and understandable for consumers than a concise summary: Market research conducted by our teams has found that ''less is more'' for Care Compare consumers, who become overwhelmed by too much information. In fact, these findings were one of the primary reasons we have transitioned from Hospice Compare and the other individual compare sites to Care Compare.

We appreciate the concern that consumers may not know about the component measure scores in the Provider Data Catalogue. As we prepare to update Care Compare for the removal of the seven measures, we will consider ways to make consumers of Care Compare aware of this additional data, if they are interested in viewing them.

Comment: Several commenters expressed concern about the public's ability to understand the meaning of the HIS Comprehensive Measure without being able to see the seven component measures. These commenters provided general and specific suggestions about how to display the HIS Comprehensive Measure on Care Compare if the seven HIS measures are removed. Several other commenters also suggested posting a disclaimer that the HIS Comprehensive measure only comes from the admission item set and may not be reflective of subsequent care.

Response: We appreciate that the presentation of the seven HIS measures helped consumers understand the content of the HIS Comprehensive Measure. As we prepare to update Care Compare for their removal, we will consider ways to revise the measure description for the HIS Comprehensive Measure on Care Compare so that it adequately explains the elements contained in the measure.

As for the request to notify consumers that the measure is based on admission alone, we do not believe this would help consumers use the measure to compare and select hospices, as intended. The HIS Comprehensive Measure, like any given quality measure, is one part of a portfolio of measures intended to provide a holistic view of care. No single quality measure within the portfolio is expected, or necessarily intended, to provide that view on its own. As we determine the most appropriate way to display the measure, we will ensure that the scope of the HIS Comprehensive Measure is clear for consumers, who can use the information with other information on the website to make their decisions.

Comment: A number of commenters suggested that CMS continue providing the option for hospices to view detailed information about the individual measures that make up the HIS Comprehensive Assessment measure to support quality improvement.

Response: We will ensure that the confidential QM reports continue to include the seven HIS process measures, in addition to the HIS Comprehensive Assessment Measure. This helps hospices apply quality improvement processes to continue improving their performance on the HIS Comprehensive Assessment Measure.

Final Decision: We are finalizing our proposal to remove the seven HIS process measures no earlier than the May 2022 refresh from public reporting on Care Compare and from the Preview Reports but continue to have them publicly available in the data catalogue.

(2). Calculating and Publicly Reporting ''Claims-Based Measure'' as Part of the HQRP

In the HIS V3.00 Paperwork Reduction Act Submission (OMB control number: 0938–1153, CMS–10390), we finalized a proposal to adopt HVLDL into the HQRP for FY 2021. We are also proposing in this rule to adopt the HCI into the HQRP for FY2022. In this section, we presented three proposals related to calculating and reporting claims-based measures, with specific application to HVLDL and HCI. First, we are finalizing our proposal to extract claims data to calculate claims-based measures at least 90 days after the last discharge date in the applicable period, which we will use for quality measure calculations and public reporting on Care Compare. For example, if the last discharge date in the applicable period for a measure is December 31, 2022, for data collection January 1, 2022, through December 31, 2022, we would create the data extract on approximately March 31, 2023, at the earliest. We would use those data to calculate and publicly report the claims-based measures for the CY2022 reporting period. This is similar to those finalized in other PAC settings, including the CY 2017 Home Health Prospective Payment System final rule (81 FR 76702), FY 2017 Inpatient Rehabilitation Facility Prospective Payment System final rule (81 FR 52056), and the FY 2017 Long Term Care Hospital Prospective Payment System final rule (81 FR 56762).

We are finalizing the proposed timeframe which allows us to balance providing timely information to the public with calculating the claims-based measures using as complete a data set as possible. We recognize the approximately 90-day ''run-out'' period is shorter than the Medicare program's current timely claims filing policy under which providers have up to 1 year from the date of discharge to submit claims. However, several months lead-time is necessary after acquiring the data to conduct the claims-based calculations. If we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to hospices sooner than 18 to 24 months after the last discharge.

To implement this process, hospices would not be able to submit corrections to the underlying claims snapshot or add claims (for those claims-based measures) to this data set at the conclusion of the 90-day period following the last date of discharge used in the applicable period. Therefore, we would consider the hospice claims data to be complete for purposes of calculating the claims-based measures at this point. Thus, it is important that hospices ensure the completeness and correctness of their claims prior to the claims ''snapshot.''

Second, we are finalizing our proposal to update the claims-based measures used for the HQRP annually. Specifically, we will refresh claims-based measure scores on Care Compare, in preview reports, and in the confidential CASPER QM preview reports annually. This periodicity of updates aligns with most claims-based measures across PAC settings.

Third, we are finalizing our proposal to calculate claims-based measure scores based on one or more years of data. We considered several factors to determine the number of years to include in measure calculations. Using only 1 year (4 quarters) of data, as is currently done for HIS-based quality measures reported on Care Compare, allows us to share with the public only the most up-to-date information and best reflects current realities. Having only the most recent data can also help incentivize hospices with lower scores to make changes and have the results of their effort be reflected in better scores.

At the same time, we want to report measures scores to the public for as many hospices as possible, including small hospices. Currently, only Medicare-certified hospices with more than 20 patient stays each year have quality measure results publicly available on Care Compare. This public reporting threshold protects the privacy

of patients who seek care at smaller hospices. However, due to the threshold, at least some hospices will not achieve the minimum patient stays within 1 year. This means that their scores will not be displayed on Care Compare, and consumers will not have information about them to inform their decisions about selecting a hospice. Using more years of data allows more of these hospices to meet this threshold.

We conducted reportability testing for HCI and HVLDL to help us consider how best to balance the need for recent data with the need for transparency in reporting the HQRP claims-based measures. Specifically, we conducted a simulation using 2 years of data. We then calculated the change in the number of hospices which achieved the minimum reporting standard. We also compared the measure scores of the hospices that meet the reporting threshold when we use 2 years of data with hospices that meet the threshold using only 1 year of data.

Results for both HCI and HVLDL indicate that using 2 years of data increases reportability. For HVLDL, combining 2 years of data (FY 2018 to FY 2019) allows an additional 326 hospices to share measure scores, or 33.8 percent of the hospices that do not meet the reporting threshold in FY 2019 alone. For HCI, combining 2 years of data (FY 2018 to FY 2019 data) allows an additional 277 to report HCI measure scores on Care Compare, or 43.2 percent of the hospices that do not meet the reporting threshold in FY 2019 alone.

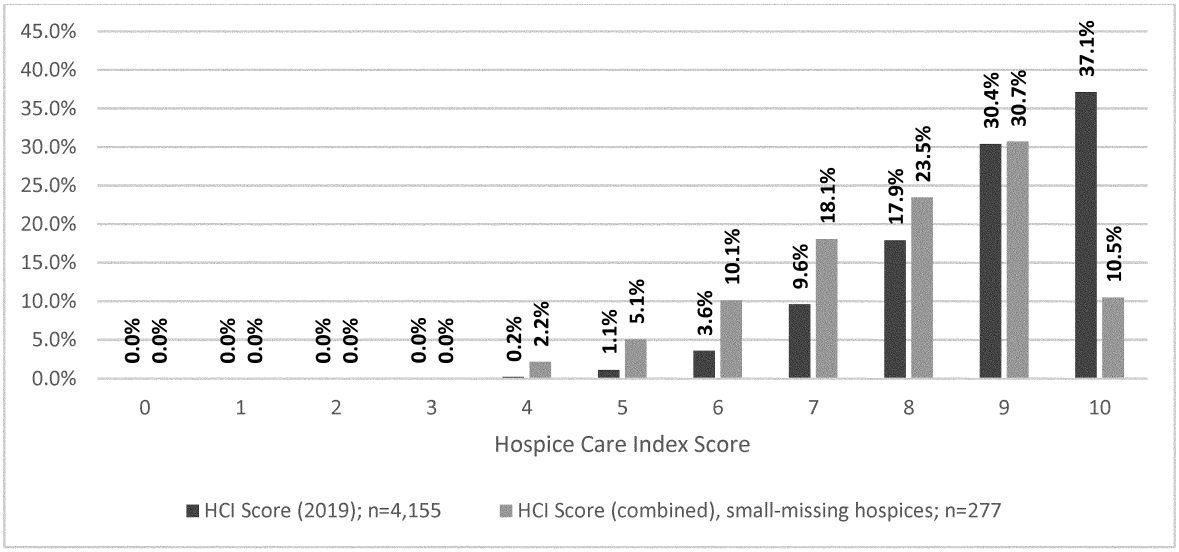
TABLE 19: Two years of Data Increases Reportability for HVLDL and HCI

Quality Measure	Excluded hospices when using one year of data (FY 2019) alone	Additional hospices meeting threshold with two years of data (FY 2018 – FY 2019), relative to FY 2019 alone	% of hospices that did not meet threshold in FY 2019
HVLDL	965	326	33.8%
HCI	641	277	43.2%

Our simulations indicate that the hospices that only meet the reporting threshold when using 2 years of data have performance scores substantially lower than average. For HVLDL, where higher scores indicate better quality of care, the national average score was 65.5 percent in FY 2019, where 965 hospices did not meet the reportability threshold. After pooling data using FY 2018 to FY 2019, 326 additional hospices met the reportability threshold, or 33.8 percent of those previously missing. Those addition 326 hospices had an average HVLDL score of just 43.3 percent, about 20 percentage points lower than the hospices meeting the reportability threshold using FY 2019 alone national average score for this HVLDL measure.

The results for HCI similarly show that the hospices with reportable data when using two-pooled years of data had lower HCI scores compared to the national average when using just FY 2019 data. Higher HCI scores indicate better performance. As Figure 2 shows, a larger numbers of hospices among the 277 hospices that only meet the reporting threshold when using 2 years of data had HCI scores between four and eight, while a larger number of hospices in the FY 2019 population had a perfect score of 10.

Figure 2: Percent of hospices meeting the public reporting threshold based on 1 (FY 2019) or 2 pooled years (FY 2018 to FY 2019) of data, by Hospice Care Index score



Source: 100% Medicare claims, Federal Fiscal Years 2018-2019.

Given these findings, we are finalizing our proposal to use 2 years of data to publicly report HCI and HVLDL in 2022. The use of 2 years or 8 quarters of quality data is already publicly reported for the quality measures related to the CAHPS Hospice Survey so hospices are familiar with this approach. We plan to consider multiple years of data, like the 2 years of data, for other claims-based measures proposed in subsequent years. We believe it is important to support consumers by sharing information on the performance of hospices that have lower scores, and to incentivize those hospices to improve. The results demonstrate that using multiple years of data help include more hospices that have lower performance rates for HVLDL and HCI in public reporting on Care Compare. While using more years of data would allow us to report measures for even more hospices, it would involve sharing data that are no longer relevant, and display scores that do not reflect recent hospice improvement efforts.

We solicited public comment on these proposals related to the use of 2 years of data for claims-based measures and public reporting of claims measures in general and their application to HVLDL and HCI specifically. We received several comments from various stakeholders on this proposal. A summary of the comments we received on this proposal and our responses to those comments appear below:

Comment: A few commenters expressed concern that hospices would not be able to view data close to real time, which might inhibit the ability to use the score to inform continuous quality improvement.

Response: We agree that there is a lag time between the delivery of care and the calculation and reporting of the claims-based quality measures, including HCI. However, the time is needed. After the data extract is created after the 90-day run-off, it takes several months to incorporate other data needed for the calculations. We then need to generate and check the calculations before posting for confidential reporting. Our proposal for using the 90-day run-off strikes a balance between allowing time for hospices to make corrections to their claims, while also seeking to post more rather than less up-to-date information. We have streamlined our processes as much as possible, and time is needed to go through these steps to ensure accurate publication of quality measure data.

Comment: Several commenters requested that CMS issue confidential reports with hospices' claims-based measure scores in CASPER to help hospices understand and validate their scores before they are publicly reported.

Response: Section 1814(i)(5)(E) of the Act requires that the Secretary establish procedures for making HQRP data available to the public and ensure that hospices have the opportunity to review HQRP data before their release to the public. We will provide this opportunity to review for claims-based measures in a process similar to HIS-based measures. Hospices can review and correct their HIS data before the Data Correction Deadline; for claims data, hospices will be able to ensure that the data are accurate through the end of the 90-day run-off period. Subsequently, as with HIS-based measures, we will implement a 30-day preview period for claims-based measures, which will serve as the final opportunity for hospices to review their data and alert CMS about any errors in the measure calculations they identify. Should a hospice believe they have found an error with an HIS or claims-based measure calculation as displayed in their preview reports, they can request a review, and we will suppress if the review finds the calculation problematic. We refer readers to the HQRP website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Public-Reporting-HIS-Preview-Reports-and-Requests-for-CMS-Review-of-HIS-Data,* which we will revise to include further information on public reporting of claims as well as HIS data. This page covers information about for accessing reports and an email address should hospices have questions regarding any of the above-mentioned reports or processes.

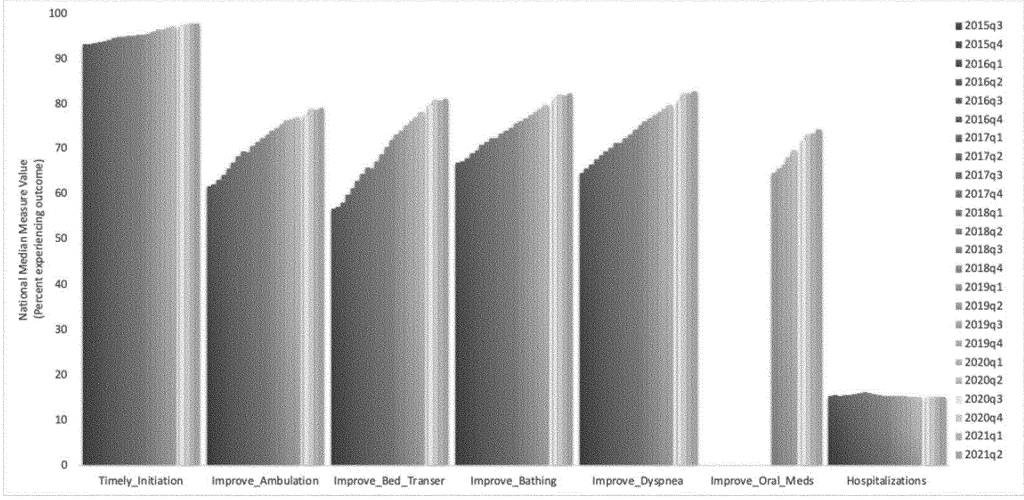
In addition to the Preview Report, we will also include claims-based measure scores in the Hospice Agency-Level QM Report in CASPER. This report is intended to support quality improvement for hospices. Measure scores will be updated annually in the QM Report as they will in the Preview Report and on Care Compare and the Provider Data Catalogue.

Comment: We received several comments with a request for CMS to consider quarterly as opposed to annual reporting of claims-based measures to best support continuous quality improvement activities.

Response: Our proposal to update annually reflects our understanding that claims measures reflect business practices that are slow to change. For example, for HCI, as we discussed in the proposed rule, we compared index scores calculated for the same hospice using annual claims from Federal FY 2017 and 2019. The analysis found that 83% of hospices had HCI scores that were 0–1 percentage points different in FY2019 relative to their FY2017 scores. These results indicate that a hospice's HCI scores would not normally fluctuate a great deal from one year to the next, and that they will fluctuate even less from quarter to quarter. Thus, quarterly updates would not necessarily provide meaningful support to hospices seeking to improve their quality of care. Instead, progress on HCI will occur over longer time frames, and annual updates are sufficient to support hospices' efforts to improve.

Other PAC settings show similar findings regarding the stability of claims measures compared to assessment scores, which we update quarterly. In the home health setting, for example, national median scores for OASIS-based measures tend to increase, while the acute care hospitalization measure remains steady (Figure 3).

Figure 3. National median values over time



At the same time, reporting claims-based measures does require additional labor. Given the findings about stability in claims measure scores, and the cost of updating more frequently, all PAC settings update claims-based measures annually. Hospital claims-based measures are also updated annually. The HQRP seeks to align with the other settings.

Given the findings and considerations, we believe that our proposal to provide annual updates is appropriate. However, we will remain open to reconsidering the frequency of reporting claims across all PAC settings in the future, should data after implementation indicate that such change is warranted.

Comment: One commenter expressed concern that CMS would obtain the data from cost reports, which would not allow them time to understand or preview the measures before they were publicly reported.

Response: We will not pull claims data for calculating the measures from cost reports. Instead, it will come from our research database that contains Medicare files including fee-for-service claims data. As stated, data source and timing will allow time for hospices to preview their measure scores before they are publicly reported.

Comment: We received comments in support of the proposal to use two years of data for publicly reporting HVLDL and HCI. One of these commenters expressed support for making the reporting more inclusive of smaller hospices, to encourage them to also improve the quality of care they provide. Other commenters suggested using a 1-year time frame, so as to make the measure score more reflective of current operations and performance, and thus more understandable and useful for providers and consumers. Some commenters recommended adding a disclaimer that the data are two years old and do not reflect the current status of hospice performance.

Response: We agree that there are benefits to reporting just one year of data. However, we also believe that we must strike a balance between the benefits of reporting fewer years of more timely data with the need to be more inclusive of smaller hospices, which MedPAC has found have higher live discharge rates than larger hospices.[50] In other settings, some claims-based measures also use two or even three years of data for reporting. For example, as part of the Home Health Quality Reporting Program, the Potentially Preventable 30-Day Post-Discharge Readmission measure is reported using three years of data, while Medicare Spending Per Beneficiary and Discharge to Community measures are reported using two years of data. We also considered using three years of data for HVLDL and HCI, and determined that three years did not yield the same benefit (that is, inclusion of hospices) relative to cost (that is, lag in reporting), and thus proposed using two years of data. With two years of data, 50 percent

[50] MedPAC. 2020. Report to the Congress: Medicare Payment Policy | March 2020. *http://medpac.gov/docs/default-source/reports/mar20_medpac_ch12_sec.pdf?sfvrsn=0.* Accessed June 13, 2021.

of the data come from the more recent year, and hospices should still be able to see their scores change as their performance improves.

Final Decision: We are finalizing as proposed our proposals to use 90-day run-off data to calculate claims-based measures, to update claims-based measure scores annually, and to use eight quarters of data to report HVLDL and HCI.

(3). Publicly Report the Hospice Care Index and ''Hospice Visits in the Last Days of Life'' Claims-Based Measures

As discussed previously, we are finalizing our proposal to publicly report the HCI and HVLDL using 2 years, which is 8 quarters of Medicare claims data. We will publicly report the HCI and HVLDL beginning no earlier than May 2022, and to include it in the Preview Reports no sooner than the May 2022 refresh. The publicly-reported version of HCI on Care Compare will only include the final HCI score, and not the component indicators. The Preview Reports will reflect the HCI as publicly reported.

We solicited public comment on this proposal for HCI and HVLDL public reporting on Care Compare no sooner than May 2022. A summary of the comments we received on this proposal and our responses to those comments appear below:

Comment: Many commenters requested clarification on the reporting period for initial reporting. They also requested clarification on the logistics of the reporting process—in particular, when specifications would be available.

Response: We appreciate the opportunity to provide clarification. If released in May 2022 using eight quarters of data, the HCI and HVLDL measure reporting period would begin with FY2021 (Q1, Q2, and Q3 2021 and Q4 2020). The next four quarters would be Q3 2020 and Q2, Q3, and Q4 of 2019—that is, past quarters adding up to eight quarters but omitting Q1 and Q2 of 2020, which were exempt from quality reporting (please see section 10.b.(2) above, ''Update on Use of Q4 2019 Data and Data Freeze for Refreshes in 2021''). As provided in sections III F(3). ''Addition of a ''claims-based index measure'', the Hospice Care Index'' and III F(4). ''Update on the Hospice Visits in the Last Days of Life (HVLDL) and Hospice Item Set V3.00'', we gave sufficient information in the proposed rule and this final rule to calculate HCI and HVLDL and access specifications. The HQRP will post a revised QM Users' Manual that contains HCI and HVLDL no later than October 1, 2021 at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.*

Comment: We received several comments expressing concern about the timing for publicly reporting HVLDL and HCI on Care Compare and the Provider Data Catalogue. Commenters requested sufficient time to understand the measures, set up monitoring systems (sometimes with vendor support), assess trends in their performance relative to national benchmarks, and develop plans for quality improvement, as CMS normally provides. One noted that this time is needed in particular because visits on claims have not previously impacted hospice quality scores or payment. Others noted that the delay could allow time for additional analysis of the measure, and for more transparency about the rationale for it. Many of these commenters requested that CMS wait a year (until 2023) to publicly report the measures, while also requesting to confidential reports with the claims-based measures as soon as possible. One commenter requested a minimum of 6 months from the date final specifications are available for EMR and other vendors to respond to any changes in the HQRP.

Response: As stated in section III F(3)(e). ''Form, Manner and Timing of Data Collection and Submission'', we have provided and will consolidate in the Users' Manual specifications for HCI and HVLDL in time to meet commenters' stated needs. In addition, we will provide hospices with confidential reporting of their HVLDL and HCI measure scores in the Agency-Level QM report after this rule is finalized—after August 2021. This would allow sufficient time to complete the activities related, which is what we normally aim to give providers to understand and prepare for public reporting of a new measure, if we publicly report in May 2022. We believe that the QM report and Provider Preview report will provide an indication on how well the hospice is performing as well as opportunities to provide CMS feedback on technical issues with the measures. To further support the hospice community, we will also provide education, training, and additional opportunities for hospices to receive information about the measures through open door forums or other venues.

Although these measures represent the first time that hospices are held accountable for visits information in claims, the measures reflect ideas about best practice and compliance that hospices have already known. While we are committed to provide time for understanding and preparation, we are not committed to ensuring that all hospices achieve high scores on the new measures before publicly reporting them. For these reasons, we believe that no additional dry run period is warranted.

Comment: A commenter suggested that CMS should not use claims data from a time period before a measure is finalized through rulemaking.

Response: Our practice across all PAC settings has been to allow the use of claims data originating from before the finalization of a proposal to adopt a claims-based measure. For example, for the Home Health QRP, we finalized the Potentially Preventable 30-Day Post-Discharge Readmission Measure in the CY 2017 Home Health QRP Rule (81 FR 76770 through 76775) for reporting with three consecutive years of claims data beginning with the CY 2018 Home Health QRP.

Comment: Commenters recommended using simple language to describe HVLDL on Care Compare, to ensure that the average consumer will understand it. For HVLDL, one commenter suggested that CMS notify consumers that the measure does not capture visits from chaplains, volunteers, hospice aides, and complementary therapies, among others. For HCI, several commenters expressed concern about CMS's ability to help consumers interpret it in a way that helps support informed decision-making. For example, an average consumer might misinterpret higher scores for live discharges or avoidance of general inpatient care as favorable.

Response: We also believe in the importance of using simple language on Care Compare to ensure consumers can easily use and appropriately interpret quality information that we provide for their decision-making. As with any measure included in the HQRP, we are committed to providing all users with the necessary information to understand the intent and application of measures in the HQRP. Before we publicly report this measure, we will provide resources to aid the public in interpreting publicly displayed quality data. For HVLDL specifically, we will list the multi-disciplinary team member visits that are included in the measure as part of the measure description displayed on Care Compare.

For the public display of HCI, our measure development contractor convened two small caregiver workgroups to gather impressions and input on the value of HCI for consumers. The caregivers were generally receptive and positive about the HCI as an additional measure for the

Hospice QRP, and expressed interest in the indicator-level information as well as the index score to better understand the hospice. Their response confirmed our understanding that the data included in HCI will be useful for patients and families as they compare and select hospice providers. Based on the caregivers' feedback, we proposed reporting the HCI as a single score to report on Care Compare, while providing the indicator scores in the Provider Data Catalog (PDC). We will continue to apply ideas shared by the Caregiver Workgroup participants as we refine plans for the measure's public display to minimize the risk of misinterpretation.

Final Decision: We are finalizing as proposed to publicly report the HCI and HVLDL beginning no earlier than May 2022, and to include it in the Preview Reports no sooner than the May 2022 refresh.

(4). Update on Publicly Reporting for the ''Hospice Visits When Death is Imminent (HVWDII) Measure 1'' and the ''Hospice Visits in the Last Days of Life (HVLDL) Measure''

As discussed earlier, the HIS V3.00 PRA Submission, CMS–10390 (OMB control number: 0938–1153), finalized the proposal to replace the HVWDII measure pair with a re-specified version called HVLDL, which is a single measure based on Medicare claims. Relatedly, in the HIS V3.00 PRA Submission, CMS–10390 (OMB control number: 0938–1153), we finalized the proposal to remove Section O from the HIS. As stated in section 1814(i)(5)(E) of the Act, we establish procedures for making all quality data submitted by hospices under § 418.312 available to the public. Thus, we would have continued to publicly report HVWDII Measure 1 data through the November 2021 refresh. Because of the data freeze, HVWDII Measure 1 data from the November 2020 refresh, covering HIS admissions during Q1 through Q4 2019, will be publicly displayed for all calendar year 2021 refreshes. We may retain the November 2020 refresh for HVWDII Measure 1 for one or more refreshes in 2022, when there will be no HIS Section O data, if doing so will allow us to consolidate changes and thus operate more efficiently.

D. Update on Transition From Hospice Compare to Care Compare and Provider Data Catalog

In September 2020, we launched Care Compare, a streamlined redesign of eight existing CMS healthcare compare tools available on *Medicare.gov,* including Hospice Compare. Care Compare provides a single user-friendly interface that patients and family caregivers can use to make informed decisions about healthcare based on cost, quality of care, volume of services, and other data. With just one click, patients can find information that is easy to understand about doctors, hospitals, nursing homes, and other health care services instead of searching through multiple tools.

For the last six years, Medicare's Hospice Compare has served as the cornerstone for publicizing quality care information for patients, family caregivers, consumers, and the healthcare community. The new website builds on the eMedicare initiative to deliver simple tools and information to current and future Medicare beneficiaries. Drawing on lessons learned through research and stakeholder feedback, Care Compare includes features and functionalities that appeal to Hospice Compare consumers. By offering an accessible and user-friendly interface and a simple design that is optimized for mobile and tablet use, it is easier than ever to find information that is important to patients when shopping for healthcare. Enhancements for mobile use will give practical benefits like accessing the tool using a smartphone that can initiate phone calls to providers simply by clicking on the provider's phone number.

In conjunction with the Care Compare launch, we have made additional improvements to other CMS data tools, to help Medicare beneficiaries compare costs. Specifically, the Provider Data Catalog (PDC) better serves innovators and stakeholders who are interested in detailed CMS data and use interactive and downloadable datasets like those currently available on *data.Medicare.gov*. The PDC now makes quality datasets available through an improved Application Programming Interface (API), allowing innovators in the field to easily access and analyze the CMS publicly-reported data and make it useful for patients.

e. Update on Additional Information on Hospices for Public Reporting

In the FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements final rule (83 FR 38622), we finalized plans to publicly post information from the Medicare Provider Utilization and Payment Data: Hospice Public Use File (PUF) and other publicly-available CMS data to Hospice Compare or another CMS website. Hospice PUF data are available for CY 2014 through CY 2016. Beginning with CY 2017 data, hospice PUF data are public as part of the Post-Acute Care and Hospice Provider Utilization and Payment PUF (hereafter PAC PUF). For more information, please visit the PAC PUF web page at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/PAC2017.* Both the Hospice and PAC PUFs provide information on services provided to Medicare beneficiaries by hospice providers. Specifically, they contain information on utilization, payment (Medicare payment and standard payment), submitted charges, primary diagnoses, sites of service, and beneficiary demographics organized by CCN (6-digit provider identification number) and state.

PUF data, along with clear text explaining the purpose and uses of this information and suggesting consumers discuss this information with their healthcare provider, first displayed in a consumer-friendly format on Hospice Compare in May 2019. Beginning May 2021, we will begin to display additional information from the PAC PUF on Care Compare. This additional information includes hospices' beneficiary characteristics such as the percentage of patients enrolled in Medicare Advantage. In addition, consumers will see whether a hospice provided services to Medicare Advantage enrollees or patients who have coverage under both Medicaid and Medicare, also called dual eligible patients. The data for these additional characteristics are pulled directly from the PAC PUF file and provide potential hospice service patients and family caregivers with more detail prior to selecting a hospice.

As finalized in the FY 2019 Hospice Wage Index and Payment Update final rule (83 FR 38622), we also improved access to publicly-available information about hospices' compliance with Hospice QRP requirements. Specifically, we already post the annual Hospice APU Compliant List on the *HQRP Requirements and Best Practices* web page. This document displays the CCN, name, and address of every hospice that successfully met quality reporting program requirements for the fiscal year. Hospices are only considered compliant if they meet the standards for HIS and CAHPS reporting, as codified in § 418.312. Consumers can now access the Hospice APU compliance file from Care Compare, enabling them to determine if a particular hospice is compliant with CMS' quality reporting requirements.

G. January 2022 HH QRP Public Reporting Display Schedule with Fewer than Standard Number of Quarters Due to COVID–19 Public Health Emergency Exemptions

1. Background and Statutory Authority

We include this Home Health proposal in this rule because we plan to resume public reporting for the HH QRP with the January 2022 refresh of Care Compare. In order to accommodate the exception of 2020 Q1 and Q2 data, we are proposing to resume public reporting using 3 out of 4 quarters of data for the January 2022 refresh. In order to finalize this proposal in time to release the required preview report related to the refresh, which we release 3 months prior to any given refresh (October 2021), we need the rule containing this proposal to finalize by October 2021.

The HH QRP is authorized by section 1895(b)(3)(B)(v) of the Act. Section 1895(b)(3)(B)(v)(II) of the Act requires that for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary shall reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP and further reduction of the increase by the productivity adjustment (except in 2018 and 2020) described in section 1886(b)(3)(B)(xi)(II) of the Act may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year. For more information on the policies we have adopted for the HH QRP, we refer readers to the following rules:

- CY 2007 HH PPS final rule (71 FR 65888 through 65891).
- CY 2008 HH PPS final rule (72 FR 49861 through 49864).
- CY 2009 HH PPS update notice (73 FR 65356).
- CY 2010 HH PPS final rule (74 FR 58096 through 58098).
- CY 2011 HH PPS final rule (75 FR 70400 through 70407).
- CY 2012 HH PPS final rule (76 FR 68574).
- CY 2013 HH PPS final rule (77 FR 67092).
- CY 2014 HH PPS final rule (78 FR 72297).
- CY 2015 HH PPS final rule (79 FR 66073 through 66074).
- CY 2016 HH PPS final rule (80 FR 68690 through 68695).
- CY 2017 HH PPS final rule (81 FR 76752).
- CY 2018 HH PPS final rule (82 FR 51711 through 51712).
- CY 2019 HH PPS final rule with comment period (83 FR 56547).
- CY 2020 HH PPS final rule (84 FR 60554 through 60611).
- CY 2021 HH PPS final rule (85 FR 70326 through 70328).

2. Public Display of Home Health Quality Data for the HH QRP

Section 1895(b)(3)(B)(v)(III) of the Act requires the Secretary to establish procedures for making HH QRP data, including data submitted under sections 1899B(c)(1) and 1899B(d)(1) of the Act, available to the public. Such public display procedures must ensure that HHAs have the opportunity to review the data that will be made public with respect to each HHA prior to such data being made public. Section 1899B(g) of the Act requires that data and information regarding PAC provider performance on quality measures and resource use or other measures be made publicly available beginning not later than 2 years after the applicable specified ''application date''.

We established our HH QRP Public Display Policy in the CY 2016 HH PPS final rule (80 FR 68709 through 68710). In that final rule, we noted that the procedures for HHAs to review and correct their data on a quarterly basis is performed through CASPER along with our procedure to post the data for the public on our Care Compare website. We have communicated our public display schedule, which supports our Public Display Policy, on our websites whereby the quarters of data included are announced.

3. Proposal To Modify HH QRP Public Reporting To Address CMS' Guidance To Except Data During the COVID–19 PHE Beginning January 2022 Through July 2024

We proposed to modify our public display schedule to display fewer quarters of data than what we previously finalized for certain HH QRP measures for the January 2022 refresh. Under authority of section 319 of the PHS Act, the Secretary declared a PHE effective as of January 27, 2020. On March 13, 2020, the President declared a national state of emergency under the Stafford Act, effective March 1, 2020, allowing the Secretary to invoke section 1135(b) of the Act (42 U.S.C. 1320b–5) to waive or modify the requirements of titles XVIII, XIX, and XXI of the Act and regulations to the extent necessary to address the COVID–19 PHE. Many waivers and modifications were made effective as of March 1, 2020 in accordance with the President's declaration.[51]

On March 27, 2020, we sent a guidance memorandum under the subject title, ''Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies (HHAs), Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19'' to the MLN Connects Newsletter and Other Program-Specific Listserv Recipients,[52] hereafter referred to as the March 27, 2020 CMS Guidance Memorandum. In the March 27, 2020 CMS Guidance Memo, we granted an exception to the HH QRP reporting requirements under the HH QRP exceptions and extension requirements for Quarter 4 (Q4) 2019 (October 1, 2019 through December 31, 2019), Q1 2020 (January 1, 2020 through March 30, 2020), and Q2 2020 (April 1, 2020 through June 30, 2020). The HH QRP exception applied to the HH QRP Outcome and Assessment Information Set (OASIS)-based measures, claims-based measures, and HH CAHPS Survey. We discuss the impact to the OASIS and claims here, and discuss to the HH CAHPS further in section III.G. 4, Update on Use of Q4 2019 HH QRP Data and Data Freeze for Refreshes in 2021. For the OASIS, the exempted quarters are based upon admission and discharge assessments.

A subset of the HH QRP measures has been publicly displayed on Home

[51] Azar, A. M. (2020 March 15). *Waiver or Modification of Requirements Under Section 1135 of the Social Security Act.* Public Health Emergency. *https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.*

[52] (2020, March 27). *Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19.* Centers for Medicare & Medicaid Services. *.https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

Health Compare (HH Compare) since 2003. Under the current HH QRP public display policy, Home Health Compare uses 4 quarters of data to publicly display OASIS-based measures, and 4 or more quarters of data to publicly display claims-based measures. We use four rolling quarters of data to publicly display Home Health Care Consumer Assessment of Healthcare Providers and Systems (HH CAHPS) Survey measures on Care Compare. As of September 2020, HH QRP OASIS, claims-based, and HH CAHPS Survey measures are reported on the *www.medicare.gov*'s Care Compare website. As of December 2020, the data is no longer reported on the *www.medicare.gov*'s Home Health Compare website.

The exception granted under the March 27, 2020 CMS Guidance Memo impacted the HH QRP public display schedule. We proposed resuming publicly displaying HH QRP claims-based measures in January 2022 based upon the quarters of data specified for each of the claims-based measures. Table 20 displays the original schedule for public reporting of OASIS and HH CAHPS Survey measures prior to the Q1 and Q2 2020 data impacted by the COVID–19 PHE.

TABLE 20: Original Public Reporting Schedule with Refreshes

Quarter Refresh	HH Quarters in Original Schedule for Care Compare	HH CAHPS Survey Quarters in Original Schedule for Care Compare
October 2020	OASIS, ACH, & ED quality measure (QM): Q1 2019- Q4 2019 DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)	Q2 2019 – Q1 2020
*January 2021	OASIS, ACH, & ED QM: Q2 2019- Q1 2020 DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)	Q3 2019 – Q2 2020
*April 2021	OASIS, ACH & ED QM: Q3 2019- Q2 2020 DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)	Q4 2019 – Q3 2020
*July 2021	OASIS, ACH & ED QM: Q4 2019-Q3 2020 DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)	Q1 2020 – Q4 2020
*October 2021	OASIS, ACH & ED QM: Q1 2020- Q4 2020 DTC, MSPB: Q1 2019- Q4 2020 (8) PPR: Q1 2018- Q4 2020 (12)	Q2 2020 – Q1 2021
*January 2022	OASIS, ACH & ED QM: Q2 2020- Q1 2021 DTC, MSPB: Q1 2019 – Q4 2020 (8) PPR: Q1 2018 – Q4 2020 (12)	Q3 2020 – Q2 2021
†*April 2022	OASIS, ACH & ED QM: Q3 2020-Q2 2021 DTC, MSPB: Q1 2019 – Q4 2020 (8) PPR: Q1 2018 – Q4 2020 (12)	Q4 2020 - Q3 2021
†July 2022	OASIS, ACH & ED QM: Q4 2020-Q3 2021 DTC, MSPB: Q1 2019- Q4 2020 (8) PPR: Q1 2018- Q4 2020 (12)	Q1 2021 - Q4 2021
†October 2022	OASIS, ACH & ED QM: Q1 2021-Q4 2021 DTC, MSPB: Q1 2020- Q4 2021 (8) PPR: Q1 2019- Q4 2021 (12)	Q2 2021 - Q1 2022
†January 2023	OASIS, ACH & ED QM: Q2 2021-Q1 2022 DTC, MSPB: Q1 2020- Q4 2021 (8) PPR: Q1 2019- Q4 2021 (12)	Q3 2021 - Q2 2022
†Apri1 2023	OASIS, ACH & ED QM: Q3 2021-Q2 2022 DTC, MSPB: Q1 2020- Q4 2021 (8) PPR: Q1 2019- Q4 2021 (12)	Q4 2021 - Q3 2022
†July 2023	OASIS, ACH & ED QM: Q4 2021-Q3 2022 DTC, MSPB: Q1 2020- Q4 2021 (8) PPR: Q1 2019- Q4 2021 (12)	Q1 2022-Q4 2022
††October 2023	OASIS, ACH, ED Use: Q1 2022-Q4 2022 DTC, MSPB: Q1 2021- Q4 2022 (8) PPR: Q1 2020- Q4 2022 (12)	Q2 2022 - Q1 2023
††January 2024	OASIS, ACH, ED Use: Q2 2022-Q1 2023 DTC, MSPB: Q1 2021- Q4 2022 (8) PPR: Q1 2020- Q4 2022 (12)	Q3 2022 -Q2 2023
††April 2024	OASIS, ACH, ED Use: Q3 2022-Q2 2023 DTC, MSPB: Q1 2021- Q4 2022 (8) PPR: Q1 2020- Q4 2022 (12)	Q4 2022-Q3 2023
†† July 2024	OASIS, ACH, ED Use: Q4 2022-Q3 2023 DTC, MSPB: Q1 2021- Q4 2022 (8) PPR: Q1 2020- Q4 2022 (12)	Q1 2023-Q4 2023
October 2024	OASIS, ACH, ED Use: Q1 2023-Q4 2023 DTC, MSPB: Q1 2022- Q4 2023 (8) PPR: Q1 2021- Q4 2023 (12)	Q2 2023 - Q1 2024

*Exceptions affect both OASIS and HH CAHPS Survey data for refresh; †Exceptions affect only HH CAHPS Survey measures and some claims-based measures for refresh; †† Exceptions affect only some claims-based measures.

During the spring and summer of 2020, we conducted testing to inform decisions about publicly displaying HH QRP data for those refreshes which include data from the exception period of October 1, 2019 through June 30,

2020 (hereafter ''excepted data''). The testing helped us develop a plan for displaying HH QRP data that are as up-to-date as possible and that also meet scientifically-acceptable standards for publicly displaying those data. We believe that the plan allows us to provide consumers with helpful information on the quality of home health care, while also making the necessary adjustments to accommodate the exception granted to HHAs. The following sections provide the results of our testing for OASIS and claims and explain how we used the results to inform a proposal for accommodating excepted data in public reporting. HH CAHPS discussion is further in section III.G.4.

4. Update on Use of Q4 2019 HH QRP Data and Data Freeze for Refreshes in 2021

In the March 27, 2020 Guidance Memorandum, we stated that we should not include any PAC quality data that are greatly impacted by the exception granted in the quality reporting programs. Given the timing of the COVID–19 PHE onset, we determined that we would not use HH QRP OASIS, claims, or HH CAHPS data from Q1 and Q2 of 2020 for public reporting, and that we would assess the impact of the COVID–19 PHE on HH QRP data from Q4 2019. In the original schedule (Table 20), the October 2020 refresh included Q4 2019 measure based on OASIS and HH CAHPS data and is the last refresh before Q1 2020 data are included.

Before proceeding with the October 2020 refresh, we conducted testing to ensure that publicly displaying Q4 2019 data would still meet our standards despite granting an exception to HH QRP reporting requirements for Q4 2019. Specifically, we compared submission rates in Q4 2019 to average rates in other quarters to assess the extent to which HHAs had taken advantage of the exception, and thus the extent to which data and measure scores might be affected. We observed that the quality data submission rate for Q4 2019 was in fact 0.4 percent higher than the previous calendar year (Q4 2018). We note that Q4 2019 ended before the onset of the COVID–19 pandemic in the U.S. Thus, we proceeded with including Q4 2019 data in measure calculations for the October 2020 refresh.

Because we excepted HHAs from the HH QRP reporting requirements for Q1 and Q2 2020, we did not use OASIS, claims, or HH CAHPS data from these quarters. All refreshes, during which we decided to hold this data constant, included more than 2 quarters of data that were affected by the CMS-issued COVID reporting exceptions, thus we did not have an adequate amount of data to reliably calculate and publicly display provider measures scores. Consequently, we determined to freeze the data displayed, that is, holding data constant after the October 2020 refresh without subsequently updating the data through October 2021. We communicated this in a Public Reporting Tip Sheet, which is located at: *https://www.cms.gov/files/document/hhqrp-pr-tip-sheet081320final-cx-508.pdf.*

5. Application of the COVID–19 PHE Affected Reporting (CAR) Scenario To Publicly Display Certain HH QRP Measures (Beginning in January 2022 Through July 2024)

We also proposed to use the CAR scenario for refreshes for January 2022 for OASIS and for refreshes from January 2022 through July 2024 for some claims-based measures. There are several forthcoming HH QRP refreshes for which the original public reporting schedule included other quarters from the quality data submission exception. These refreshes for claims-based measures, OASIS-based measures, and for HH CAHPS Survey measures are outlined in Table 20.

Because October 2020 refresh data will become increasingly out-of-date and thus less useful for the public, we analyzed whether it would be possible to use fewer quarters of data for one or more refreshes and thus reduce the number of refreshes that continue to display October 2020 data. Using fewer quarters of more up-to-date data requires that: (1) A sufficient percentage of HHAs would still likely have enough OASIS data to report quality measures (reportability); and (2) using fewer quarters of data to calculate measures would likely produce similar measure scores for HHAs, and thus not unfairly represent the quality of care HHAs provided during the period reported in a given refresh (reliability).

To assess these criteria, we conducted reportability and reliability analysis excluding the COVID–19 affected quarters of data in a refresh instead of the standard number of quarters of data for reporting for each HH QRP measure to model the impact of not using Q1 or Q2 2020 Specifically, we used historical data to calculate HH quality measures under two scenarios:

- Standard Public Reporting (SPR) Scenario: We used HH QRP data from CY 2017 through 2019 to build the standard reported measures, to represent as a proxy CY 2020 public reporting in the absence of the temporary exemptions from the submission of OASIS quality data, as the basis for comparing simulated alternatives. This entails using 4 quarters of CY 2019 HH QRP data to model the OASIS based measures that are normally calculated using 4 quarters of data. This also entailed using 4 quarters of HH QRP data from CY 2019 for the all-cause hospitalization and emergency department use claims-based measures, 8 quarters of HH QRP data from CY2018 and CY2019 for Medicare spending per beneficiary (MSPB) and discharge to community (DTC) claims-based measures; and or 12 quarters from January 2017 to December 2019 for the potentially preventable readmission claims-based measure.
- COVID–19 Affected Reporting (CAR) Scenario: We calculated OASIS-based measures using 3 quarters of HH QRP CY 2019 data to simulate using only Q3 2020, Q4 2020, and Q1 2021 data for public reporting. We calculated claims-based measures using HH QRP CY 2017 to 2019 data, to simulate using the most recent data while excluding the same quarters (Q1 and Q2) that are relevant from the COVID–19 PHE exception. We used 3 quarters of HH QRP data from CY 2019 for the all-cause hospitalization and emergency department use claims-based measures and 6 quarters of data from HH QRP CY 2018 and CY 2019 were used for both the Medicare spending per beneficiary and discharge to community claims-based measures. We used 10 quarters of HH QRP data from CY 2017 to 2019 to calculate the CAR scenario for the potentially preventable readmissions claims-based measure. For both claims and OASIS-based measures, the quarters used in our analysis were the most recently available data that exclude the same quarters (Q1 and Q2) as that are relevant from the COVID–19 PHE exception, and thus take seasonality into consideration.

The OASIS-based measures are based on the start of care and calculated using admission dates. Therefore, under the CAR scenario we excluded data for OASIS-based measures for HHA patient stays with admission dates in Q1 and Q2 2019. To assess performance in these scenarios, we calculated the reportability as the percent of HHAs meeting the 20-case minimum for public reporting (the public reporting threshold, or ''PRT''). We evaluated measure reliability using the Pearson and Spearman correlation coefficients, which assess the alignment of HHs measure scores between scenarios. To calculate the reliability results, we restricted the HHAs included in the SPR Scenario to those included in the CAR Scenario.

Testing results showed that using the CAR scenario would achieve scientifically acceptable quality measure scores for the HH QRP. As displayed in Table 21, the percentage of HHAs that met the public display threshold for the OASIS-based measure decreases by 5.5 percentage points or less for all but one QM, the Influenza Immunization for the Current Flu Season in the CAR scenario versus SPR scenario. CMS has traditionally used a reportability threshold of 70 percent, meaning at least 70 percent of HHAs are able to report at least 20 episodes for a given measure, as the standard to determine whether a measure should be publicly reported. By this standard, we consider a decrease of 5.5 percentage points or less scientifically acceptable. The change in reportability for the Influenza Immunization for the Current Flu Season measure is related to the seasonality of this measure, which includes cases that occur during the flu season only.

Under the CAR scenario, the January 2022 refresh data would cover Q3 and Q4 of 2020 and Q1 of 2021, which occur during the flu season. This simulation included Q2 through Q4 of 2019, which crosses the flu season. Thus, the reportability of the actual data used is likely to be better than this simulation. Therefore, in general, using CAR scenario for the OASIS and claims-based measures would achieve acceptable reportability for the HH QRP measures. Testing also yielded correlation coefficients above 0.85, indicating a high degree of agreement between HH measure scores when using the CAR scenario or the SPR scenario.

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TABLE 21: HH QRP Measure Results Under the SPR and CAR Scenarios

	Reportability			Reliability	
Measure Reference Name	**% providers meeting PRT (Standard Public Reporting, SPR Scenario)**	**% providers meeting PRT (COVID-19 Affected Reporting, CAR Scenario)**	**Change in % Providers meeting PRT**	**Pearson Correlation**	**Spearman Correlation**
Application of Percent of Long Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF 2631)	86.2	81.9%	4.3%	.97	.91
Changes in Skin Integrity Post-Acute Care Pressure Ulcers/Injuries	80.9%	75.9%	5%	.85	.87
Drug Regimen Review	86.2%	81.9%	4.3%	.99	.96
Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674)	86.1%	81.7%	4.4%	.89	.88
Influenza Immunization Received for Current Flu Season	81.9%	70.7%	11.2%	.92	.90
Timely Initiation of Care (NQF #0526)	86.2%	81.9%	4.3%	.97	.95
Improvement in Ambulation (NQF #0167)	80.4%	75.6%	4.8%	.98	.97
Improvement in Bed Transfer (NQF 175)	80.1%	75.2%	4.9%	.98	.97
Improvement in Bathing (NQF #0174)	80.8%	75.7%	5.1%	.98	.97
Improvement in Dyspnea	79.1%	73.6%	5.5%	.98	.97
Improvement in Management of Oral Medications (NQF #0176)	79.1%	73.8%	5.3%	.98	.97
Discharge to Community (DTC) (NQF 3477)	86.5	81.7	4.8%	.95	.96
Medicare Spending per Beneficiary (MSPB)	91.3	89.8	1.5%	.94	.94

	Reportability			Reliability	
Measure Reference Name	**% providers meeting PRT (Standard Public Reporting, SPR Scenario)**	**% providers meeting PRT (COVID-19 Affected Reporting, CAR Scenario)**	**Change in % Providers meeting PRT**	**Pearson Correlation**	**Spearman Correlation**
Acute care Hospitalization (AH) (NQF #0171)	80.9	75.8	5.1%	.88	.87
Emergency Department Use (EDU) (NQF # 0173)	80.9	75.8	5.1%	.91	.90

We proposed to use the CAR scenario for the last of the refreshes affecting OASIS-based measures, which will occur in January 2022. We also proposed to use the CAR scenario for refreshes from January 2022 through July 2024 for some claims-based measures.

Our proposal to adopt the CAR scenario for the January 2022 refresh would allow us to begin displaying recent data in January 2022, rather than continue displaying October 2020 data (Q1 2019 through Q4 2019). We believe that updating the data in January 2022 by more than a year relative to the October 2020 freeze data can assist the public by providing more relevant quality data and allow CMS to display more recent HHA performance. Similarly, using fewer than standard numbers of quarters for claims-based measures that typically use eight or twelve months of data for reporting between January 2022 and July 2024 will allow us to begin providing more relevant data sooner. Our testing results indicate we can achieve these positive impacts while maintaining high standards for reportability and reliability. Table 22 and Table 23 summarize the comparison between the original schedule for public reporting with the revised schedule (that is, frozen data) and also with the proposed public display schedule under the CAR scenario (that is, using 3 quarters in the January 2022 refresh), for OASIS- and claims-based measures respectively.

TABLE 22: Original, Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exceptions for HH OASIS-based QMs

Quarter Refresh	**OASIS Quarters in Original Schedule for Care Compare (number of quarters)**	**OASIS Quarters in revised/proposed Schedule for Care Compare (number of quarters)**
October 2020	Q1 2019- Q4 2019 (4)	Q1 2019- Q4 2019 (4)
January 2021	Q2 2019- Q1 2020 (4)	Q1 2019- Q4 2019 (4)
April 2021	Q3 2019-Q2 2020 (4)	Q1 2019- Q4 2019 (4)
July 2021	Q4 2019- Q3 2020 (4)	Q1 2019- Q4 2019 (4)
October 2021	Q1 2020- Q4 2020 (4)	Q1 2019- Q4 2019 (4)
January 2022*	Q2 2020-Q1 2021 (4)	Q3 2020-Q1 2021 (3)

Note: The shades cells represent data frozen due to the COVID-19 PHE.
* OASIS data with 3 versus 4 quarters of data

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TABLE 23: Original, Revised, and Example Schedule for Refreshes Affected by COVID-19 PHE Exceptions for HH Claims-based QMs

Quarter Refresh *Dates are for example only---Actual Dates will be provided sub-regulatory	Claims-based Quarters in Original Schedule for Care Compare (number of quarters)	Claims-based Quarters in revised/proposed Schedule for Care Compare (number of quarters) *Quarters are for example only---Actual Quarters will be provided sub-regulatory
October 2020	ACH, ED Use: Q1 2019- Q4 2019 (4) DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)	ACH, ED Use: Q1 2019- Q4 2019 (4) DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)
January 2021	ACH, ED Use: Q2 2019- Q1 2020 (4) DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)	ACH, ED Use: Q1 2019- Q4 2019 (4) DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)
April 2021	ACH, ED Use: Q3 2019-Q2 2020 (4) DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)	ACH, ED Use: Q1 2019- Q4 2019 (4) DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)
July 2021	ACH, ED Use: Q4 2019- Q3 2020 (4) DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)	ACH, ED Use: Q1 2019- Q4 2019 (4) DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)
October 2021	ACH, ED Use: Q1 2020- Q4 2020 (4) DTC, MSPB: Q1 2019- Q4 2020 (8) PPR: Q1 2018- Q4 2020 (12)	ACH, ED Use: Q1 2019- Q4 2019 (4) DTC, MSPB: Q1 2018- Q4 2019 (8) PPR: Q1 2017- Q4 2019 (12)
January 2022*	ACH, ED Use: Q2 2020-Q1 2021 (4) DTC, MSPB: Q1 2019- Q4 2020 (8) PPR: Q1 2018- Q4 2020 (12)	ACH, ED Use: Q3 2020-Q1 2021 (3) DTC, MSPB: Q1 2019- Q4 2019; Q3 2020 –Q4 2020 (6) PPR: Q1 2018-Q4 2019 Q3 2020 – Q4 2020 (10)
October 2022*	ACH, ED Use: Q1 2021-Q4 2021 (4) DTC, MSPB: Q1 2020- Q4 2021 (8) PPR: Q1 2019- Q4 2021 (12)	ACH, ED Use: Q1 2021-Q4 2021 (4) DTC, MSPB: Q3 2020 –Q4 2020 (6) PPR: Q1 2019-Q4 2019 Q3 2020 – Q4 2021 (10)
October 2023*	ACH, ED Use: Q1 2022-Q4 2022 (4) DTC, MSPB: Q1 2021- Q4 2022 (8) PPR: Q1 2020- Q4 2022 (12)	ACH, ED Use: Q1 2022-Q4 2022 (4) DTC, MSPB: Q1 2021- Q4 2022; (8) PPR: Q3 2020-Q4 2020 Q1 2021 – Q4 2022 (10)
October 2024†	ACH, ED Use: Q1 2023-Q4 2023 (4) DTC, MSPB: Q1 2022- Q4 2023 (8) PPR: Q1 2021- Q4 2023 (12)	ACH, ED Use: Q1 2023-Q4 2023 (4) DTC, MSPB: Q1 2022- Q4 2023 (8) PPR: Q1 2021- Q4 2023 (12)

Note: The shades cells represent data frozen due to COVID-19 PHE. DTC, MSPB and PPR measures are updated annually in October.

* Refreshes with few quarters of certain claims data.

† Refresh with the original public reporting schedule resuming for claims data.

We solicited public comments on the proposal to use the CAR scenario to publicly report HH OASIS in January 2022 and claims-based measures beginning with the January 2022 through July 2024 refreshes. A summary of the comments we received on this proposal and our responses to those comments appear below:

Comment: We received many comments supporting HH QRP reporting to resume beginning January 2022. One commenter suggested including a statement that data cover care provided during the COVID–19 PHE for eight quarters.

Response: We thank commenters for their support of this proposal on public reporting for refreshes affected by the exceptions. However, we do not agree with the commenter who suggested including a statement on Care Compare regarding the inclusion of data from the COVID–19 PHE because such an announcement will not help consumers distinguish between HHAs in their region. Instead, we will continue to post state and national averages for HH QRP measures. This information will help consumers understand relative performance at national and local levels in light of the COVID–19 PHE.

Given the overall positive response to our proposal, we believe that the proposed approach balances fairness to providers with a commitment to transparency and information for consumers.

Final Decision: We are finalizing our proposal to use the CAR scenario for refreshes for January 2022 for OASIS-based measures and for refreshes from

January 2022 through July 2024 for some claims-based measures.

6. Update to the Public Display of HH CAHPS Measures Due to the COVID–19 PHE Exception

Since April 2012, we have publicly displayed four quarters of HH CAHPS data every quarter, in the months of January, April, July, and October. The COVID–19 PHE Exception applied to Q1 and Q2 of 2020. Those excepted quarters cannot be publicly displayed and resulted in the freezing of the public display using Q1 2019 through Q4 2019 data for the refreshes that would have occurred from October 2020 through October 2021, as shown in Table 24. Beginning with January 2022, we will resume reporting four quarters of HH CAHPS data. The data for the January 2022 refresh are Q3 2020 through Q2 2021. These are the same quarters that would have been publicly displayed despite the COVID–19 PHE. Table 24 summarizes this discussion.

TABLE 24: HH CAHPS Public Reporting Quarters During and After the Freeze

Refresh	Publicly Reported Quarters
Freeze:	Q1 2019 - Q4 2019
October 2020-October 2021*	Q1 2019 – Q4 2019
January 2022**	Q3 2020-Q2 2021
April 2022	Q4 2020-Q3 2021
July 2022	Q1 2021-Q4 2021
October 2022	Q2 2021-Q1 2022
January 2023	Q3 2021-Q2 2022
April 2023	Q4 2021-Q3 2022
July 2023	Q1 2022-Q4 2022
*The grey shading refers to the frozen quarters.	
**Resume rolling of most recent four rolling quarters of data. These are the same rolling quarters that would have displayed regardless of the COVID-19 PHE.	

IV. Requests for Information

A. Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Post-Acute Care Quality Reporting Programs—Request for Information

Through the proposed rule, we sought input on the following steps that would enable transformation of CMS' quality measurement enterprise to be fully digital (86 FR 19765):

a. What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?

b. How do you currently share information with other providers and are there specific industry best practices for integrating SDOH screening into EHR's?

c. What ways could we incentivize or reward innovative uses of health information technology (IT) that could reduce burden for post-acute care settings, including but not limited to hospices?

d. What additional resources or tools would post-acute care settings, including but not limited to hospices and health IT vendors find helpful to support testing, implementation, collection, and reporting of all measures using FHIR standards via secure APIs to reinforce the sharing of patient health information between care settings?

e. Would vendors, including those that service post-acute care settings, including but not limited to hospices, be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would align standards for quality measure data collection across care settings to improve care coordination, such as sharing patient data via secure FHIR API as the basis for calculating and reporting digital measures?

f. What could be the potential use of FHIR dQMs that could be adopted across all QRPs?

We plan to continue working with other agencies and stakeholders to coordinate and to inform our

transformation to dQMs leveraging health IT standards. While we stated that we would not be responding to specific comments submitted in response to this Request for Information in the FY 2022 Hospice Wage Index final rule, we will actively consider all input as we develop future regulatory proposals or future sub-regulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice- and-comment rulemaking, as necessary.

Comments: We received many comments expressing support for the adoption of a standardized definition of dQM in the hospice setting and the use of Fast Healthcare Interoperability Resources (FHIR) to support quality measurements in the HQRP. Many commenters noted that there is a great deal of variation among FHIR systems, which could impede the adoption of a standard system across hospices. Commenters also expressed issues surrounding interoperability capabilities of EHR vendor systems noting that currently, some EHR vendors do not include features important for interoperability as a part of their base product, which would represent additional costs for hospices which can lead to affordability issues for many providers. Furthermore, commenters noted that interoperability challenges lead to complications when sharing health information with other providers. They encouraged HHS to continue pursuing adoption of FHIR APIs for health IT vendors.

We also received several comments responding to how CMS should incentivize the use of HIT. Commenters noted that hospices were not included in the EHR Incentive Program, which provided grants to hospices to develop HIT systems. We received many comments emphasizing that financial incentives would encourage providers to adopt new HIT systems and work to reduce burden using FHIR and EHR. Commenters also encouraged CMS to provide early testing and education for providers on HIT and to provide a structured FHIR transition framework for key stakeholders.

We also received several comments explaining the various EHR/HIT systems currently in use, as well as discussions surrounding health information exchange with other providers.

Response: While we stated that we would not be responding to specific comments submitted in response to this RFI in the FY 2022 Hospice Wage Index final rule, we appreciate all of the comments and interest in this topic. We will continue to take all concerns, comments, and suggestions into account as we consider Fast Healthcare Interoperability Resources (FHIR) in support of Digital Quality Measurement in Post-Acute Care Quality Reporting Programs.

B. Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs—Request for Information

While hospice is not included in the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act of 2014) (Pub. L. 113–185), we sought comment on the possibility of revising measure development, and the collection of other data that address gaps in health equity in HQRP (86 FR 19766). Any potential health equity data collection or measure reporting within a CMS program that might result from public comments received in response to this solicitation would be addressed through a separate notice-and-comment rulemaking in the future. We invited public comment on the following:

- Recommendations for quality measures, or measurement domains that address health equity, for use in the HQRP.
- Suggested parts of SDOH standardized patient assessment data elements adoption that could apply to hospice in alignment with national data collection and interoperable exchange standards. This could include collecting information on race, ethnicity, and certain SDOH, including preferred language, interpreter services, health literacy, transportation and social isolation. This could also include guidance on any additional items, including standardized patient assessment and data elements that could be used to assess health equity in the care of hospice patients, for use in the HQRP.
- Ways CMS can promote health equity in outcomes among hospice patients. We were also interested in feedback regarding whether including facility-level quality measure results stratified by social risk factors and social determinants of health (and relevant proxies, such as dual eligibility for Medicare and Medicaid, and race) in confidential feedback reports could allow facilities to identify gaps in the quality of care they provide. (For example, methods similar or analogous to the CMS Disparity Methods which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmission Reduction Program (84 FR 42496 through 42500)).
- Methods that commenters or their organizations use in employing data to reduce disparities and improve patient outcomes, including the source(s) of data used, as appropriate.
- Given the importance of structured data and health IT standards for the capture, use, and exchange of relevant health data for improving health equity, the existing challenges providers' encounter for effective capture, use, and exchange of health information, such as data on race, ethnicity, and other social determinants of health, to support care delivery and decision making.

While we stated that we would not be responding to specific comments submitted in response to this RFI in the FY 2022 Hospice Wage Index final rule, we appreciate all of the comments and interest in this topic. We will continue to take all concerns, comments, and suggestions into account as we continue work to address and develop policies on this important topic. It is our hope to provide additional stratified information to providers related to race and ethnicity if feasible. The provision of stratified measure results will allow hospices to understand how they are performing with respect to certain patient risk groups, to support these providers in their efforts to ensure equity for all of their patients, and to identify opportunities for improvements in health outcomes.

2. Public Comments Summarized

We received many comments about the use of standardized patient assessment data in the hospice setting to assess health equity and social determinants of health (SDOH). Many commenters noted a 2019 Abt Associates and RAND Corporation study which excluded hospices from the standardized data elements for patient assessment denominator, citing that hospice patients have a different goal of care which does not align with standardized data elements for patient assessment. Commenters encouraged CMS to only utilize certain aspects of standardized data elements for patient assessment (specifically, Z-codes 55–65) in collecting health equity data. We also received some comments which expressed that standardized data elements for patient assessment does not currently capture the current understanding of SDOH.

We also received feedback from several commenters about additional factors which should be considered when collecting data about health equity and disparities. We noted several categories, including: culture, spiritual beliefs, food insecurity, access to interpreter services, health literacy,

caregiving, housing scarcity, marital status, and socioeconomic status. Commenters encouraged CMS to stratify quality measures by demographic data, social risk factors, and social determinants of health.

We also noted a comment encouraging CMS to implement a best-practice assessment for the collection of demographic and SDOH data. A commenter noted that there is not a standard initial nursing or social worker assessment that currently screens for SDOH.

One commenter also expressed a desire to include permanent telehealth provisions in the QRP, as that would help improve rural healthcare access.

We appreciate all the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into consideration for future development and expansion of our health equity quality measurement efforts.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the provisions of the rule are finalized, either as proposed or as amended in response to public comments, and take effect, in accordance with the Administrative Procedure Act (APA) (Pub. L. 79–404), 5 U.S.C. 553, and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Further, 5 U.S.C. 553 requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and a period of not less than 60 days for public comment for rulemaking carrying out the administration of the insurance programs under title XVIII of the Act. Section 1871(b)(2)(C) of the Act and 5 U.S.C. 553 authorize the agency to waive these procedures, however, if the agency for good cause finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We are revising the provisions at § 418.306(b)(2) to change the payment reduction for failing to meet hospice quality reporting requirements from 2 to 4 percentage points. This policy will apply beginning with FY 2024 annual payment update (APU). Specifically, the Act requires that, beginning with FY 2014 through FY 2023, the Secretary shall reduce the market basket update by 2 percentage points and beginning with the FY 2024 APU and for each subsequent year, the Secretary shall reduce the market basket update by 4 percentage points for any hospice that does not comply with the quality data submission requirements for that FY. We noted this revised statutory requirement in our proposed rule (86 FR 19726) and are codifying the revision at § 418.306(b)(2). While we received comments, this update is statutorily required and self-implementing. Notice and comment are unnecessary because we are conforming the regulation to statute and there is no discretion on the part of the Secretary.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to 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.

A. ICRs Regarding Hospice QRP

We are revising the provisions at § 418.306(b)(2) to change the payment reduction for failing to meet hospice quality reporting requirements from 2 to 4 percentage points. This policy will apply beginning with FY 2024 annual payment update (APU). Specifically, the Act requires that, beginning with FY 2014 through FY 2023, the Secretary shall reduce the market basket update by 2 percentage points and beginning with the FY 2024 APU and for each subsequent year, the Secretary shall reduce the market basket update by 4 percentage points for any hospice that does not comply with the quality data submission requirements for that FY. We noted this revised statutory requirement in our proposed rule (86 FR 19726) and are codifying the revision at § 418.306(b)(2). While we received comments, this update is statutorily required and self-implementing. Notice and comment are unnecessary because we are conforming the regulation to statute and there is no discretion on the part of the Secretary. The HQRP proposals would not change provider burden or costs.

- For the proposal to remove the 7 HIS measures from the HQRP, we do not propose any changes to the requirement to submit the HIS admission assessment since we continue to collect the data for these 7 HIS measures in order to calculate the more broadly applicable NQF # 3235, the Hospice and Palliative Care Composite Process Measure—HIS-Comprehensive Assessment Measure at Admission.
- The proposal to add the HCI also would not change provider burden or costs since it is a claims-based measure that CMS calculates from the Medicare claims data.
- Likewise, the proposal to publicly report the claims-based HVLDL quality measure would not result in reduced provider burden and related costs. The reduction in provider burden and costs occurred when we replaced the HIS-based HVWDII quality measure via the HIS-information collection request (ICR) –CMS–10390 (OMB Control Number: 0938–1153 (Expiration date: February 29, 2024).
- Finally, the Home Health proposal would not change provider burden or costs since it only affects the number of quarters used in the calculation of certain claims-based measures for the public display for certain refresh cycles.

B. ICRs Regarding Hospice CoPs

We are revising the provisions at § 418.76(c)(1) that requires the hospice aide to be evaluated by observing an aide's performance of the task with a patient. This revision is subject to the PRA; however, the information collection burden associated with the existing requirements at § 418.76(c)(1) are accounted for under the information collection request currently approved OMB control number 0938–1067 (Expiration date: March 31, 2024). We requested public comment in determining if the time and effort necessary to comply with implementing the use of the pseudo-patient for hospice aide training at § 418.76(c)(1)

would reduce burden on the provider. While comments were overwhelmingly supportive, we did not receive any comments that would support burden changes.

We are also revising the provisions at § 418.76(h)(1)(iii) to state that if an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete, a competency evaluation related to the deficient and related skill(s) in accordance with § 418.76(c). While many commenters indicated that the proposed changes increase efficiency of training, none provided specific information or data to describe a change in burden. Additionally, we believe that both the requirements at § 418.76(h) are exempt from the PRA. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe competency evaluations are a usual and customary business practice and we state as such in the information collection request associated with the Hospice CoPs—CMS–10277 (OMB control number 0938–1067). Therefore, we are not seeking OMB approval for any information collection or recordkeeping activities that may be conducted in connection with the revisions to § 418.76(h).

VII. Regulatory Impact Analysis

A. Statement of Need

This final rule meets the requirements of our regulations at § 418.306(c) and (d), which require annual issuance, in the **Federal Register**, of the hospice wage index based on the most current available CMS hospital wage data, including any changes to the definitions of CBSAs or previously used MSAs, as well as any changes to the methodology for determining the per diem payment rates. This final rule also updates payment rates for each of the categories of hospice care, described in § 418.302(b), for FY 2022 as required under section 1814(i)(1)(C)(ii)(VII) of the Act. The payment rate updates are subject to changes in economy-wide productivity as specified in section 1886(b)(3)(B)(xi)(II) of the Act. Lastly, section 3004 of the Affordable Care Act amended the Act to authorize a quality reporting program for hospices, and this rule discusses changes in the requirements for the HQRP in accordance with section 1814(i)(5) of the Act.

B. Overall Impacts

We estimate that the aggregate impact of the payment provisions in this rule will result in an increase of $480 million in payments to hospices, resulting from the hospice payment update percentage of 2.0 percent for FY 2022. The impact analysis of this rule represents the projected effects of the changes in hospice payments from FY 2021 to FY 2022. Using the most recent complete data available at the time of rulemaking, in this case FY 2020 hospice claims data as of January 15, 2021, we apply the current FY 2021 wage index with the current labor shares. Using the same FY 2020 data, we apply the FY 2022 wage index and the current labor share values to simulate FY 2022 payments. We then apply a budget neutrality adjustment so that the aggregate simulated payments do not increase or decrease due to changes in the wage index. Then, using the same FY 2020 data, we apply the FY 2022 wage index and the current labor share values to simulate FY 2022 payments and compare simulated payments using the FY 2022 wage index and the proposed revised labor shares. We then apply a budget neutrality adjustment so that the aggregate simulated payments do not increase or decrease due to changes in the labor share values.

Certain events may limit the scope or accuracy of our impact analysis, because such an analysis is susceptible to forecasting errors due to other changes in the forecasted impact time period. The nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon hospices.

We have examined the impacts of this rule 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 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), 5 U.S.C. 804(2). Accordingly, we have prepared a RIA that, to the best of our ability presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

1. Hospice Payment Update for FY 2022

The FY 2022 hospice payment impacts appear in Table 25. We tabulate the resulting payments according to the classifications (for example, provider type, geographic region, facility size), and compare the difference between current and future payments to determine the overall impact. The first column shows the breakdown of all hospices by provider type and control (non-profit, for-profit, government, other), facility location, facility size. The second column shows the number of hospices in each of the categories in the first column. The third column shows the effect of using the FY 2022 updated wage index data. This represents the effect of moving from the FY 2021 hospice wage index to the FY 2022 hospice wage index. The fourth column shows the effect of the final rebased labor shares. The aggregate impact of the changes in column three and four is zero percent, due to the hospice wage index standardization factor and the

labor share standardization factor. However, there are distributional effects of the FY 2022 hospice wage index. The fifth column shows the effect of the hospice payment update percentage as mandated by section 1814(i)(1)(C) of the Act, and is consistent for all providers. The 2.0 hospice payment update percentage is based on the 2.7 percent inpatient hospital market basket update, reduced by a 0.7 percentage point productivity adjustment. The sixth column shows the effect of all the proposed changes on FY 2022 hospice payments. It is projected that aggregate payments would increase by 2.0 percent; assuming hospices do not change their billing practices. As illustrated in Table 25, the combined effects of all the proposals vary by specific types of providers and by location.

In addition, we are providing a provider-specific impact analysis file, which is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Hospice-Regulations-and-Notices.html.* We note that simulated payments are based on utilization in FY 2020 as seen on Medicare hospice claims (accessed from the CCW in May 2021) and only include payments related to the level of care and do not include payments related to the service intensity add-on.

As illustrated in Table 25, the combined effects of all the proposals vary by specific types of providers and by location.

TABLE 25: Impact to Hospices for FY 2022

Hospice Subgroup	Hospices	FY 2022 Updated Wage Data	FY 2022 Labor Share	FY 2022 Hospice Payment Update (%)	Overall Total Impact for FY 2022
All Hospices	4,995	0.0%	0.0%	2.0%	2.0%
Hospice Type and Control					
Freestanding/Non-Profit	597	0.0%	0.0%	2.0%	2.0%
Freestanding/For-Profit	3,273	0.0%	0.0%	2.0%	2.0%
Freestanding/Government	39	0.2%	0.0%	2.0%	2.2%
Freestanding/Other	370	-0.3%	0.0%	2.0%	1.7%
Facility/HHA Based/Non-Profit	361	0.0%	0.0%	2.0%	2.0%
Facility/HHA Based/For-Profit	189	0.1%	0.1%	2.0%	2.2%
Facility/HHA Based/Government	88	0.0%	0.4%	2.0%	2.4%
Facility/HHA Based/Other	78	0.4%	-0.1%	2.0%	2.3%
Subtotal: Freestanding Facility Type	4,279	0.0%	0.0%	2.0%	2.0%
Subtotal: Facility/HHA Based Facility Type	716	0.1%	0.0%	2.0%	2.1%
Subtotal: Non-Profit	958	0.0%	0.0%	2.0%	2.0%
Subtotal: For Profit	3,462	0.0%	0.0%	2.0%	2.0%
Subtotal: Government	127	0.1%	0.1%	2.0%	2.2%
Subtotal: Other	448	-0.2%	0.0%	2.0%	1.8%
Hospice Type and Control: Rural					
Freestanding/Non-Profit	138	-0.1%	0.3%	2.0%	2.2%
Freestanding/For-Profit	355	-0.2%	0.4%	2.0%	2.2%
Freestanding/Government	19	0.2%	0.3%	2.0%	2.5%
Freestanding/Other	48	-0.4%	0.5%	2.0%	2.1%
Facility/HHA Based/Non-Profit	146	-0.3%	0.3%	2.0%	2.0%
Facility/HHA Based/For-Profit	44	0.3%	0.4%	2.0%	2.7%
Facility/HHA Based/Government	66	-0.1%	0.3%	2.0%	2.2%
Facility/HHA Based/Other	45	0.3%	0.3%	2.0%	2.6%
Facility Type and Control: Urban					
Freestanding/Non-Profit	459	0.0%	-0.1%	2.0%	1.9%

Freestanding/For-Profit	2,918	0.1%	0.0%	2.0%	2.1%
Freestanding/Government	20	0.1%	-0.1%	2.0%	2.0%
Freestanding/Other	322	-0.3%	0.0%	2.0%	1.7%
Facility/HHA Based/Non-Profit	215	0.1%	-0.1%	2.0%	2.0%
Facility/HHA Based/For-Profit	145	0.1%	0.1%	2.0%	2.2%
Facility/HHA Based/Government	22	0.2%	0.4%	2.0%	2.6%
Facility/HHA Based/Other	33	0.5%	-0.2%	2.0%	2.3%
Hospice Location: Urban or Rural					
Rural	861	-0.2%	0.4%	2.0%	2.2%
Urban	4,134	0.0%	0.0%	2.0%	2.0%
Hospice Location: Region of the Country (Census Division)					
New England	156	-0.6%	-0.2%	2.0%	1.2%
Middle Atlantic	277	-0.7%	-0.1%	2.0%	1.2%
South Atlantic	582	0.3%	0.2%	2.0%	2.5%
East North Central	563	-0.2%	0.1%	2.0%	1.9%
East South Central	258	-0.2%	0.5%	2.0%	2.3%
West North Central	409	0.0%	0.2%	2.0%	2.2%
West South Central	981	-0.3%	0.3%	2.0%	2.0%
Mountain	506	0.2%	0.0%	2.0%	2.2%
Pacific	1,214	0.5%	-0.8%	2.0%	1.7%
Outlying	49	-1.4%	2.3%	2.0%	2.9%
Hospice Size					
0 - 3,499 RHC Days (Small)	1,120	0.1%	-0.2%	2.0%	1.9%
3,500-19,999 RHC Days (Medium)	2,232	0.0%	0.0%	2.0%	2.0%
20,000+ RHC Days (Large)	1,643	0.0%	0.0%	2.0%	2.0%

Source: FY 2020 hospice claims data from CCW accessed on May 11, 2021.

Region Key:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
Pacific= Alaska, California, Hawaii, Oregon, Washington
Outlying=Guam, Puerto Rico, Virgin Islands

2. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this 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 the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this final rule. We also

recognize that different types of entities are in many cases affected by mutually exclusive sections of the final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11–9111); we estimate that the cost of reviewing this rule is $114.24 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). This final rule consists of approximately 72,000 words. Assuming an average reading speed of 250 words per minute, it would take approximately 2.4 hours for the staff to review half of it. For each hospice that reviews the rule, the estimated cost is $274.18 (2.4 hour × $114.24). Therefore, we estimate that the total cost of reviewing this regulation is $14,531.54 ($274.18 × 53 reviewers).

D. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 26, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 26 provides our best estimate of the possible changes in Medicare payments under the hospice benefit as a result of the policies in this rule. This estimate is based on the data for 4,995 hospices in our impact analysis file, which was constructed using FY 2020 claims available in May 2021. All expenditures are classified as transfers to hospices.

TABLE 26: Accounting Statement: Classification of Estimated Transfers and Costs, From FY 2021 to FY 2022

Category	Transfers
Annualized Monetized Transfers	$ 480 million*
From Whom to Whom?	Federal Government to Medicare Hospices

*The net increase of $480 million in transfer payments is a result of the 2.0 percent hospice payment update compared to payments in FY 2021.

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities by meeting the Small Business Administration (SBA) definition of a small business (in the service sector, having revenues of less than $8.0 million to $41.5 million in any 1 year), or being nonprofit organizations. For purposes of the RFA, we consider all hospices as small entities as that term is used in the RFA. The Department of Health and Human Services practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The effect of the FY 2022 hospice payment update percentage results in an overall increase in estimated hospice payments of 2.0 percent, or $480 million. The distributional effects of the final FY 2022 hospice wage index do not result in a greater than 5 percent of hospices experiencing decreases in payments of 3 percent or more of total revenue. Therefore, the Secretary has certified that this rule will not create a significant economic impact on a substantial number of small entities.

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 604 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 MSA and has fewer than 100 beds. This rule will only affect hospices. Therefore, the Secretary has certified that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals (see Table 25).

F. Unfunded Mandates Reform Act (UMRA)

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. In 2021, that threshold is approximately $158 million. This rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $158 million or more in any 1 year.

G. Federalism

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 requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

H. Conclusion

We estimate that aggregate payments to hospices in FY 2022 will increase by $480 million as a result of the market basket update, compared to payments in FY 2021. We estimate that in FY 2022, hospices in urban areas will experience, on average, 2.0 percent increase in estimated payments compared to FY 2021. While hospices in rural areas will experience, on average, 2.2 percent increase in estimated payments compared to FY 2021. Hospices providing services in the Outlying and South Atlantic regions would experience the largest estimated increases in payments of 2.9 percent and 2.5 percent, respectively. Hospices serving patients in areas in the New England and Middle Atlantic regions would experience, on average, the

lowest estimated increase of 1.2 percent in FY 2022 payments.

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

I, Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 23, 2021.

List of Subjects in 42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below.

PART 418—HOSPICE CARE

■ 1. The authority citation for part 418 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 418.3 is amended by adding definitions for ''Pseudo-patient'' and ''Simulation'' in alphabetical order to read as follows:

§ 418.3 Definitions.

* * * * *

Pseudo-patient means a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the hospice aide trainee, and must demonstrate the general characteristics of the primary patient population served by the hospice in key areas such as age, frailty, functional status, cognitive status and care goals.

* * * * *

Simulation means a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

* * * * *

■ 3. Section 418.24 is amended by:

■ a. Revising paragraphs (c) introductory text and (c)(9);

■ b. Adding paragraph (c)(10);

■ c. Redesignating paragraphs (d) through (g) as paragraphs (e) through (h); and

■ d. Adding a new paragraph (d).

The revisions and additions read as follows:

§ 418.24 Election of hospice care.

* * * * *

(c) *Content of hospice election statement addendum.* For hospice elections beginning on or after October 1, 2020, in the event that the hospice determines there are conditions, items, services, or drugs that are unrelated to the individual's terminal illness and related conditions, the individual (or representative), non-hospice providers furnishing such items, services, or drugs, or Medicare contractors may request a written list as an addendum to the election statement. The election statement addendum must include the following:

* * * * *

(9) Name and signature of the individual (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not the individual's (or representative's) agreement with the hospice's determinations. If the beneficiary (or representative) refuses to sign the addendum, the hospice must document on the addendum the reason the addendum was not signed and the addendum would become part of the patient's medical record. If a non-hospice provider or Medicare contractor requests the addendum, the non-hospice provider or Medicare contractor are not required to sign the addendum.

(10) Date the hospice furnished the addendum.

(d) *Timeframes for the hospice election statement addendum.* (1) If the addendum is requested within the first 5 days of a hospice election (that is, in the first 5 days of the hospice election date), the hospice must provide this information, in writing, to the individual (or representative), non-hospice provider, or Medicare contractor within 5 days from the date of the request.

(2) If the addendum is requested during the course of hospice care (that is, after the first 5 days of the hospice election date), the hospice must provide this information, in writing, within 3 days of the request to the requesting individual (or representative), non-hospice provider, or Medicare contractor.

(3) If there are any changes to the plan of care during the course of hospice care, the hospice must update the addendum and provide these updates, in writing, to the individual (or representative) in order to communicate these changes to the individual (or representative).

(4) If the individual dies, revokes, or is discharged within the required timeframe for furnishing the addendum (as outlined in paragraphs (d)(1) and (2) of this section, and before the hospice has furnished the addendum, the addendum would not be required to be furnished to the individual (or representative). The hospice must note the reason the addendum was not furnished to the patient and the addendum would become part of the patient's medical record if the hospice has completed it at the time of discharge, revocation, or death.

(5) If the beneficiary dies, revokes, or is discharged prior to signing the addendum (as outlined in paragraphs (d)(1) and (2) of this section), the addendum would not be required to be signed in order for the hospice to receive payment. The hospice must note (on the addendum itself) the reason the addendum was not signed and the addendum would become part of the patient's medical record.

* * * * *

■ 4. Section 418.76 is amended by revising paragraphs (c)(1) and (h)(1)(iii) to read as follows:

§ 418.76 Condition of participation: Hospice aide and homemaker services.

* * * * *

(c) * * *

(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient or pseudo-patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a hospice aide with a patient or a pseudo-patient during a simulation.

* * * * *

(h) * * *

(1) * * *

(iii) If an area of concern is verified by the hospice during the on-site visit, then the hospice must conduct, and the hospice aide must complete, a competency evaluation of the deficient skill and all related skill(s) in accordance with paragraph (c) of this section.

* * * * *

■ 5. Section 418.306 is amended by revising paragraph (b)(2) to read as follows:

§ 418.306 Annual update of the payment rates and adjustment for area wage differences.

* * * * *

(b) * * *

(2) For fiscal years 2014 and through 2023, in accordance with section 1814(i)(5)(A)(i) of the Act, in the case of a Medicare-certified hospice that does not submit hospice quality data, as specified by the Secretary, the payment rates are equal to the rates for the previous fiscal year increased by the applicable hospice payment update percentage increase, minus 2 percentage points. Beginning with fiscal year 2024 and subsequent fiscal years, the reduction increases to 4 percentage points. Any reduction of the percentage change will apply only to the fiscal year involved and will not be taken into account in computing the payment amounts for a subsequent fiscal year.

* * * * *

■ 6. Section 418.309 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 418.309 Hospice aggregate cap.

* * * * *

(a) * * *

(1) For accounting years that end on or before September 30, 2016 and end on or after October 1, 2030, the cap amount is adjusted for inflation by using the percentage change in the medical care expenditure category of the Consumer Price Index (CPI) for urban consumers that is published by the Bureau of Labor Statistics. This adjustment is made using the change in the CPI from March 1984 to the fifth month of the cap year.

(2) For accounting years that end after September 30, 2016, and before October 1, 2030, the cap amount is the cap amount for the preceding accounting year updated by the percentage update to payment rates for hospice care for services furnished during the fiscal year beginning on the October 1 preceding the beginning of the accounting year as determined pursuant to section 1814(i)(1)(C) of the Act (including the application of any productivity or other adjustments to the hospice percentage update).

* * * * *

■ 7. Section 418.312 is amended by revising paragraph (b) to read as follows:

§ 418.312 Data submission requirements under the hospice quality reporting program.

* * * * *

(b) *Submission of Hospice Quality Reporting Program data.* (1) Standardized set of admission and discharge items Hospices are required to complete and submit an admission Hospice Item Set (HIS) and a discharge HIS for each patient to capture patient-level data, regardless of payer or patient age. The HIS is a standardized set of items intended to capture patient-level data.

(2) Administrative data, such as Medicare claims data, used for hospice quality measures to capture services throughout the hospice stay, are required and fulfill the HQRP requirements for § 418.306(b).

(3) CMS may remove a quality measure from the Hospice QRP based on one or more of the following factors:

(i) Measure performance among hospices is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

(ii) Performance or improvement on a measure does not result in better patient outcomes.

(iii) A measure does not align with current clinical guidelines or practice.

(iv) The availability of a more broadly applicable (across settings, populations, or conditions) measure for the particular topic.

(v) The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(vi) The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(vii) Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the program.

* * * * *

Dated: July 27, 2021.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2021–16311 Filed 7–29–21; 4:15 pm]

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Part VI

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; FY 2022 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2021 (FY 2022); Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1750–F]

RIN 0938–AU40

Medicare Program; FY 2022 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2021 (FY 2022)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPF), which include psychiatric hospitals and excluded psychiatric units of an acute care hospital or critical access hospital. This rule also updates and clarifies the IPF teaching policy with respect to IPF hospital closures and displaced residents and finalizes a technical change to one of the 2016-based IPF market basket price proxies. In addition, this final rule finalizes proposals on quality measures and reporting requirements under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program. We note that this final rule does not finalize two proposals to remove quality measures. The changes finalized in this rule for the IPFQR Program are effective for IPF discharges occurring during the Fiscal Year (FY) beginning October 1, 2021 through September 30, 2022 (FY 2022).

DATES: These regulations are effective on October 1, 2021.

FOR FURTHER INFORMATION CONTACT:

The IPF Payment Policy mailbox at *IPFPaymentPolicy@cms.hhs.gov* for general information.

Mollie Knight (410) 786–7948 or Eric Laib (410) 786–9759, for information regarding the market basket update or the labor related share.

Nick Brock (410) 786–5148 or Theresa Bean (410) 786–2287, for information regarding the regulatory impact analysis.

Lauren Lowenstein, (410) 786–4507, for information regarding the inpatient psychiatric facilities quality reporting program.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

Addendum A to this final rule summarizes the FY 2022 IPF PPS payment rates, outlier threshold, cost of living adjustment factors (COLA) for Alaska and Hawaii, national and upper limit cost-to-charge ratios, and adjustment factors. In addition, the B Addenda to this final rule shows the complete listing of ICD–10 Clinical Modification (CM) and Procedure Coding System (PCS) codes, the FY 2022 IPF PPS comorbidity adjustment, and electroconvulsive therapy (ECT) procedure codes. The A and B Addenda are available online at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html*.

Tables setting forth the FY 2022 Wage Index for Urban Areas Based on Core-Based Statistical Area (CBSA) Labor Market Areas and the FY 2022 Wage Index Based on CBSA Labor Market Areas for Rural Areas are available exclusively through the internet, on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPPS/WageIndex.html*.

I. Executive Summary

A. Purpose

This final rule updates the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPFs) for discharges occurring during FY 2022 beginning October 1, 2021 through September 30, 2022. This rule also updates and clarifies the IPF teaching policy with respect to IPF hospital closures and displaced residents and finalizes a technical change to one of the 2016-based IPF market basket price proxies. In addition, the final rule finalizes proposals to adopt quality measures and reporting requirements under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

B. Summary of the Major Provisions

1. Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS)

For the IPF PPS, we are finalizing our proposal to—

- Update IPF PPS teaching policy with respect to IPF hospital closures and displaced residents.
- Replace one of the price proxies currently used for the For-profit Interest cost category in the 2016-based IPF market basket with a similar price proxy.
- Adjust the 2016-based IPF market basket update (2.7 percent) for economy-wide productivity (0.7 percentage point) as required by section 1886(s)(2)(A)(i) of the Social Security Act (the Act), resulting in a final IPF payment rate update of 2.0 percent for FY 2022.
- Make technical rate setting changes: The IPF PPS payment rates will be adjusted annually for inflation, as well as statutory and other policy factors. This final rule updates:

++ The IPF PPS Federal per diem base rate from $815.22 to $832.94.

++ The IPF PPS Federal per diem base rate for providers who failed to report quality data to $816.61.

++ The Electroconvulsive therapy (ECT) payment per treatment from $350.97 to $358.60.

++ The ECT payment per treatment for providers who failed to report quality data to $351.57.

++ The labor-related share from 77.3 percent to 77.2 percent.

++ The wage index budget-neutrality factor from 0.9989 to 1.0017.

++ The fixed dollar loss threshold amount from $14,630 to $14,470 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF PPS payments.

2. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In this final rule, we are:

- Adopting voluntary patient-level data reporting for chart-abstracted measures for data submitted for the FY 2023 payment determination and mandatory patient-level data reporting for chart-abstracted measures for the FY 2024 payment determination and subsequent years;
- Revising our regulations at 42 CFR 412.434(b)(3) by replacing the term ''QualityNet system administrator'' with ''QualityNet security official'';
- Adopting the Coronavirus disease 2019 (COVID–19) Vaccination Coverage Among Health Care Personnel (HCP) measure for the FY 2023 payment determination and subsequent years;
- Adopting the Follow-up After Psychiatric Hospitalization (FAPH) measure for the FY 2024 payment determination and subsequent years; and
- Removing the following two measures for FY 2024 payment determination and subsequent years:

++ Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure and

++ Follow-up After Hospitalization for Mental Illness (FUH) measure.

- Not finalizing our proposals to remove the following two measures for

FY 2024 payment determination and subsequent years:

++ Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention Provided (SUB–2/2a) measure; and

++ Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB–2/2a) measure.

C. Summary of Impacts

Provision Description	Total Transfers & Cost Reductions
FY 2022 IPF PPS payment update	The overall economic impact of this final rule is an estimated $80 million in increased payments to IPFs during FY 2022.
FY 2023 IPFQR Program update.	The overall economic impact of the IPFQR Program provisions of this final rule is an estimated $512,065 reduction in information collection burden.

II. Background

A. Overview of the Legislative Requirements of the IPF PPS

Section 124 of the Medicare, Medicaid, and State Children's Health Insurance Program Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) required the establishment and implementation of an IPF PPS. Specifically, section 124 of the BBRA mandated that the Secretary of the Department of Health and Human Services (the Secretary) develop a per diem Prospective Payment System (PPS) for inpatient hospital services furnished in psychiatric hospitals and excluded psychiatric units including an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and excluded psychiatric units. ''Excluded psychiatric unit'' means a psychiatric unit of an acute care hospital or of a Critical Access Hospital (CAH), which is excluded from payment under the Inpatient Prospective Payment System (IPPS) or CAH payment system, respectively. These excluded psychiatric units will be paid under the IPF PPS.

Section 405(g)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) extended the IPF PPS to psychiatric distinct part units of CAHs.

Sections 3401(f) and 10322 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 10319(e) of that Act and by section 1105(d) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to jointly as ''the Affordable Care Act'') added subsection (s) to section 1886 of the Act.

Section 1886(s)(1) of the Act titled ''Reference to Establishment and Implementation of System,'' refers to section 124 of the BBRA, which relates to the establishment of the IPF PPS.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the rate year (RY) beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY.

Section 1886(s)(2)(A)(ii) of the Act required the application of an ''other adjustment'' that reduced any update to an IPF PPS base rate by a percentage point amount specified in section 1886(s)(3) of the Act for the RY beginning in 2010 through the RY beginning in 2019. As noted in the FY 2020 IPF PPS final rule, for the RY beginning in 2019, section 1886(s)(3)(E) of the Act required that the other adjustment reduction be equal to 0.75 percentage point; this was the final year the statute required the application of this adjustment. Because FY 2021, was a RY beginning in 2020, FY 2021 was the first-year section 1886(s)(2)(A)(ii) did not apply since its enactment.

Sections 1886(s)(4)(A) through (D) of the Act require that for RY 2014 and each subsequent RY, IPFs that fail to report required quality data with respect to such a RY will have their annual update to a standard Federal rate for discharges reduced by 2.0 percentage points. This may result in an annual update being less than 0.0 for a RY, and may result in payment rates for the upcoming RY being less than such payment rates for the preceding RY. Any reduction for failure to report required quality data will apply only to the RY involved, and the Secretary will not take into account such reduction in computing the payment amount for a subsequent RY. More information about the specifics of the current Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program is available in the FY 2020 IPF PPS and Quality Reporting Updates for Fiscal Year Beginning October 1, 2019 final rule (84 FR 38459 through 38468).

To implement and periodically update these provisions, we have published various proposed and final rules and notices in the **Federal Register**. For more information regarding these documents, see the Center for Medicare & Medicaid (CMS) website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html?redirect=/InpatientPsychFacilPPS/.*

B. Overview of the IPF PPS

The November 2004 IPF PPS final rule (69 FR 66922) established the IPF PPS, as required by section 124 of the BBRA and codified at 42 CFR part 412, subpart N. The November 2004 IPF PPS final rule set forth the Federal per diem base rate for the implementation year (the 18-month period from January 1, 2005 through June 30, 2006), and provided payment for the inpatient operating and capital costs to IPFs for covered psychiatric services they furnish (that is, routine, ancillary, and capital costs, but not costs of approved educational activities, bad debts, and

other services or items that are outside the scope of the IPF PPS). Covered psychiatric services include services for which benefits are provided under the fee-for-service Part A (Hospital Insurance Program) of the Medicare program.

The IPF PPS established the Federal per diem base rate for each patient day in an IPF derived from the national average daily routine operating, ancillary, and capital costs in IPFs in FY 2002. The average per diem cost was updated to the midpoint of the first year under the IPF PPS, standardized to account for the overall positive effects of the IPF PPS payment adjustments, and adjusted for budget-neutrality.

The Federal per diem payment under the IPF PPS is comprised of the Federal per diem base rate described previously and certain patient- and facility-level payment adjustments for characteristics that were found in the regression analysis to be associated with statistically significant per diem cost differences with statistical significance defined as p less than 0.05. A complete discussion of the regression analysis that established the IPF PPS adjustment factors can be found in the November 2004 IPF PPS final rule (69 FR 66933 through 66936).

The patient-level adjustments include age, Diagnosis-Related Group (DRG) assignment, and comorbidities; additionally, there are adjustments to reflect higher per diem costs at the beginning of a patient's IPF stay and lower costs for later days of the stay. Facility-level adjustments include adjustments for the IPF's wage index, rural location, teaching status, a cost-of-living adjustment for IPFs located in Alaska and Hawaii, and an adjustment for the presence of a qualifying emergency department (ED).

The IPF PPS provides additional payment policies for outlier cases, interrupted stays, and a per treatment payment for patients who undergo electroconvulsive therapy (ECT). During the IPF PPS mandatory 3-year transition period, stop-loss payments were also provided; however, since the transition ended as of January 1, 2008, these payments are no longer available.

C. Annual Requirements for Updating the IPF PPS

Section 124 of the BBRA did not specify an annual rate update strategy for the IPF PPS and was broadly written to give the Secretary discretion in establishing an update methodology. Therefore, in the November 2004 IPF PPS final rule, we implemented the IPF PPS using the following update strategy:

- Calculate the final Federal per diem base rate to be budget-neutral for the 18-month period of January 1, 2005 through June 30, 2006.
- Use a July 1 through June 30 annual update cycle.
- Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.

In November 2004, we implemented the IPF PPS in a final rule that published on November 15, 2004 in the **Federal Register** (69 FR 66922). In developing the IPF PPS, and to ensure that the IPF PPS can account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and certain patient and facility characteristics to determine those characteristics associated with statistically significant cost differences on a per diem basis. That regression analysis is described in detail in our November 28, 2003 IPF proposed rule (68 FR 66923; 66928 through 66933) and our November 15, 2004 IPF final rule (69 FR 66933 through 66960). For characteristics with statistically significant cost differences, we used the regression coefficients of those variables to determine the size of the corresponding payment adjustments.

In the November 15, 2004 final rule, we explained the reasons for delaying an update to the adjustment factors, derived from the regression analysis, including waiting until we have IPF PPS data that yields as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We indicated that we did not intend to update the regression analysis and the patient-level and facility-level adjustments until we complete that analysis. Until that analysis is complete, we stated our intention to publish a notice in the **Federal Register** each spring to update the IPF PPS (69 FR 66966).

On May 6, 2011, we published a final rule in the **Federal Register** titled, ''Inpatient Psychiatric Facilities Prospective Payment System—Update for Rate Year Beginning July 1, 2011 (RY 2012)'' (76 FR 26432), which changed the payment rate update period to a RY that coincides with a FY update. Therefore, final rules are now published in the **Federal Register** in the summer to be effective on October 1. When proposing changes in IPF payment policy, a proposed rule would be issued in the spring, and the final rule in the summer to be effective on October 1. For a detailed list of updates to the IPF PPS, we refer readers to our regulations at 42 CFR 412.428.

The most recent IPF PPS annual update was published in a final rule on August 4, 2020 in the **Federal Register** titled, ''Medicare Program; FY 2021 Inpatient Psychiatric Facilities Prospective Payment System and Special Requirements for Psychiatric Hospitals for Fiscal Year Beginning October 1, 2020 (FY 2021)'' (85 FR 47042), which updated the IPF PPS payment rates for FY 2021. That final rule updated the IPF PPS Federal per diem base rates that were published in the FY 2020 IPF PPS Rate Update final rule (84 FR 38424) in accordance with our established policies.

III. Provisions of the FY 2022 IPF PPS Final Rule and Responses to Comments

A. Final Update to the FY 2021 Market Basket for the IPF PPS

1. Background

Originally, the input price index that was used to develop the IPF PPS was the ''Excluded Hospital with Capital'' market basket. This market basket was based on 1997 Medicare cost reports for Medicare participating inpatient rehabilitation facilities (IRFs), IPFs, long-term care hospitals (LTCHs), cancer hospitals, and children's hospitals. Although ''market basket'' technically describes the mix of goods and services used in providing health care at a given point in time, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies) derived from that market basket. Accordingly, the term market basket as used in this document, refers to an input price index.

Since the IPF PPS inception, the market basket used to update IPF PPS payments has been rebased and revised to reflect more recent data on IPF cost structures. We last rebased and revised the IPF market basket in the FY 2020 IPF PPS rule, where we adopted a 2016-based IPF market basket, using Medicare cost report data for both Medicare participating freestanding psychiatric hospitals and psychiatric units. We refer readers to the FY 2020 IPF PPS final rule for a detailed discussion of the 2016-based IPF PPS market basket and its development (84 FR 38426 through 38447). References to the historical market baskets used to update IPF PPS payments are listed in the FY 2016 IPF PPS final rule (80 FR 46656).

2. Final FY 2022 IPF Market Basket Update

For FY 2022 (that is, beginning October 1, 2021 and ending September 30, 2022), we proposed to update the IPF PPS payments by a market basket

increase factor with a productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act. In the FY 2022 IPF proposed rule (86 FR 19483), we proposed to use the same methodology described in the FY 2021 IPF PPS final rule (85 FR 47045 through 47046), with one proposed modification to the 2016-based IPF market basket.

For the price proxy for the For-profit Interest cost category of the 2016-based IPF market basket, we proposed to use the iBoxx AAA Corporate Bond Yield index instead of the Moody's AAA Corporate Bond Yield index. Effective for December 2020, the Moody's AAA Corporate Bond series is no longer available for use under license to IHS Global Inc. (IGI), the nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and multi-factor productivity (MFP). Since IGI is no longer licensed to use and publish the Moody's series, IGI was required to discontinue the publication of the associated historical data and forecasts of this series. Therefore, IGI constructed a bond yield index (iBoxx) that closely replicates the Moody's corporate bond yield indices currently used in the market baskets.

In the FY 2022 IPF PPS proposed rule, we stated that because the iBoxx AAA Corporate Bond Yield index captures the same technical concept as the current corporate bond proxy and tracks similarly to the current measure that is no longer available, we believed that the iBoxx AAA Corporate Bond Yield index is technically appropriate to use in the 2016-based IPF market basket.

Based on IGI's fourth quarter 2020 forecast with historical data through the third quarter of 2020, the proposed 2016-based IPF market basket increase factor for FY 2022 was projected to be 2.3 percent. We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket update or MFP), we would use such data, if appropriate, to determine the FY 2022 market basket update in this final rule.

Section 1886(s)(2)(A)(i) of the Act requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, 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 sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''productivity adjustment''). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* for the BLS historical published MFP data. A complete description of the MFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Dataand-Systems/Statistics-Trends-andReports/MedicareProgramRatesStats/MarketBasketResearch.html*. We note that effective with FY 2022 and forward, CMS is changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We note that the adjustment relies on the same underlying data and methodology. This new terminology is more consistent with the statutory language described in section 1886(s)(2)(A)(i) of the Act.

Using IGI's fourth quarter 2020 forecast, the productivity adjustment for FY 2022 was projected to be 0.2 percent. We proposed to then reduce the proposed 2.3 percent IPF market basket update by the estimated productivity adjustment for FY 2022 of 0.2 percentage point. Therefore, the proposed FY 2022 IPF update was equal to 2.1 percent (2.3 percent market basket update reduced by the 0.2 percentage point productivity adjustment). Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket or MFP), we would use such data, if appropriate, to determine the FY 2022 market basket update and productivity adjustment in this final rule.

Based on the more recent data available for this FY 2022 IPF final rule (that is, IGI's second quarter 2021 forecast of the 2016-based IPF market basket with historical data through the first quarter of 2021), we estimate that the IPF FY 2022 market basket update is 2.7 percent. The current estimate of the productivity adjustment for FY 2022 is 0.7 percentage point. Therefore, the current estimate of the FY 2022 IPF increase factor is equal to 2.0 percent (2.7 percent market basket update reduced by 0.7 percentage point productivity adjustment).

We invited public comment on our proposals for the FY 2022 market basket update and productivity adjustment. The following is a summary of the public comments received on the proposed FY 2022 market basket update and productivity adjustment and our responses:

Comment: One commenter supported the update to the IPF payment rates of 2.1 percent.

Response: We thank the commenter for their support.

Comment: One commenter stated that given the growing behavioral health and substance abuse crisis made worse by the COVID–19 Public Health Emergency (PHE), that CMS should provide additional payment for IPFs in the future.

Response: We understand the commenter's concern. We acknowledge that the COVID–19 PHE has amplified the growing need for behavioral health services in this country and remain committed to trying to find ways to mitigate its impact on IPFs. Our goal is to ensure that the IPF payment rates accurately reflect the best available data. For example, as discussed in section VI.C.3 of this final rule, in comparing and analyzing FY 2019 and FY 2020 claims, we determined that the COVID–19 PHE appears to have significantly impacted the FY 2020 IPF claims such that the FY 2019 claims are the best available data to set the outlier fixed dollar loss threshold for FY 2022. Therefore, we deviated from our longstanding practice of using the most recent available year of claims, that is, FY 2020 claims, for estimating IPF PPS payments in FY 2022. We will continue to analyze more recent available IPF claims data to better understand both the short- and long-term effects of the COVID–19 PHE on the IPF PPS.

Final Decision: After consideration of the comments we received, we are finalizing a FY 2022 IPF update equal to 2.0 percent based on the more recent data available.

3. Final FY 2022 IPF Labor-Related Share

Due to variations in geographic wage levels and other labor-related costs, we believe that payment rates under the IPF PPS should continue to be adjusted by a geographic wage index, which would apply to the labor-related portion of the Federal per diem base rate (hereafter referred to as the labor-related share). The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We proposed to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2016-based IPF market basket, we proposed to calculate the labor-related share for FY 2022 as the sum of the FY 2022 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related relative importance from the 2016-based IPF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the 2016-based IPF labor-related share, see the FY 2020 IPF PPS final rule (84 FR 38445 through 38447).

The relative importance reflects the different rates of price change for these cost categories between the base year (FY 2016) and FY 2022. Based on IGI's fourth quarter 2020 forecast of the 2016-based IPF market basket, the sum of the FY 2022 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-related; Administrative and Facilities Support Services; Installation Maintenance & Repair Services; and All Other: Labor related Services was 74.0 percent. We proposed that the portion of Capital-Related costs that are influenced by the local labor market is 46 percent. Since the relative importance for Capital-Related costs was 6.7 percent of the 2016-based IPF market basket for FY 2022, we proposed to take 46 percent of 6.7 percent to determine the labor-related share of Capital-Related costs for FY 2022 of 3.1 percent. Therefore, we proposed a total labor-related share for FY 2022 of 77.1 percent (the sum of 74.0 percent for the labor-related share of operating costs and 3.1 percent for the labor-related share of Capital-Related costs). We also proposed that if more recent data became available after publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the labor-related share), we would use such data, if appropriate, to determine the FY 2022 IPF labor-related share in the final rule.

Based on IGI's second quarter 2021 forecast of the 2016-based IPF market basket, the sum of the FY 2022 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-related; Administrative and Facilities Support Services; Installation Maintenance & Repair Services; and All Other: Labor-related Services is 74.1 percent. Since the relative importance for Capital-Related costs is 6.7 percent of the 2016-based IPF market basket for FY 2022, we take 46 percent of 6.7 percent to determine the labor-related share of Capital-Related costs for FY 2022 of 3.1 percent. Therefore, the current estimate of the total labor-related share for FY 2022 is equal to 77.2 percent (the sum of 74.1 percent for the labor-related share of operating costs and 3.1 percent for the labor-related share of Capital-Related costs). Table 1 shows the final FY 2022 labor-related share and the final FY 2021 labor-related share using the 2016-based IPF market basket relative importance.

TABLE 1: FY 2022 IPF Labor-Related Share and FY 2021 IPF Labor-Related Share

	Relative importance, labor-related share, FY 2021[1]	Relative importance, labor-related share, FY 2022[2]
Wages and Salaries	52.9	52.8
Employee Benefits	13.6	13.6
Professional Fees: Labor-related	4.3	4.3
Administrative and Facilities Support Services	0.6	0.6
Installation, Maintenance and Repair	1.3	1.3
All Other Labor-related Services	1.5	1.5
Capital-related (.46)	3.1	3.1
Total	77.3	77.2

1. Based on the 2nd quarter 2020 IHS Global Inc. forecast of the 2016-based IPF market basket.
2. Based on the 2nd quarter 2021 IHS Global Inc. forecast of the 2016-based IPF market basket.

We invited public comments on the proposed labor-related share for FY 2022.

Comment: Several commenters supported the decrease in the labor-related share from 77.3 percent in FY 2021 to 77.1 percent in FY 2022 noting that it will help any facility that has a wage index less than 1.0. The commenters stated that, across this country there is a growing disparity between high-wage and low-wage states. Recognizing this disparity and slightly lowering the labor-related share provides some aid to hospitals in many rural and underserved communities.

Response: We thank the commenter for their support. We agree with the commenters that the labor-related share should reflect the proportion of costs that are attributable to labor and vary geographically to account for differences in labor-related costs across geographic areas. More recent data became available; therefore, based on IGI's second quarter 2021 forecast with historical data through the first quarter 2021 the FY 2022 labor-related share for the final rule is 77.2 percent as shown in Table 1.

After consideration of comments received, we are finalizing the use of the sum of the FY 2022 relative importance

for the labor-related cost categories based on the most recent forecast (IGI's second quarter 2021 forecast) of the 2016-based IPF market basket labor-related share cost weights, as proposed.

B. Final Updates to the IPF PPS Rates for FY Beginning October 1, 2021

The IPF PPS is based on a standardized Federal per diem base rate calculated from the IPF average per diem costs and adjusted for budget-neutrality in the implementation year. The Federal per diem base rate is used as the standard payment per day under the IPF PPS and is adjusted by the patient-level and facility-level adjustments that are applicable to the IPF stay. A detailed explanation of how we calculated the average per diem cost appears in the November 2004 IPF PPS final rule (69 FR 66926).

1. Determining the Standardized Budget-Neutral Federal per Diem Base Rate

Section 124(a)(1) of the BBRA required that we implement the IPF PPS in a budget-neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the budget-neutrality factor by setting the total estimated IPF PPS payments to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the November 2004 IPF PPS final rule (69 FR 66926).

Under the IPF PPS methodology, we calculated the final Federal per diem base rate to be budget-neutral during the IPF PPS implementation period (that is, the 18-month period from January 1, 2005 through June 30, 2006) using a July 1 update cycle. We updated the average cost per day to the midpoint of the IPF PPS implementation period (October 1, 2005), and this amount was used in the payment model to establish the budget-neutrality adjustment.

Next, we standardized the IPF PPS Federal per diem base rate to account for the overall positive effects of the IPF PPS payment adjustment factors by dividing total estimated payments under the TEFRA payment system by estimated payments under the IPF PPS. In addition, information concerning this standardization can be found in the November 2004 IPF PPS final rule (69 FR 66932) and the RY 2006 IPF PPS final rule (71 FR 27045). We then reduced the standardized Federal per diem base rate to account for the outlier policy, the stop loss provision, and anticipated behavioral changes. A complete discussion of how we calculated each component of the budget-neutrality adjustment appears in the November 2004 IPF PPS final rule (69 FR 66932 through 66933) and in the RY 2007 IPF PPS final rule (71 FR 27044 through 27046). The final standardized budget-neutral Federal per diem base rate established for cost reporting periods beginning on or after January 1, 2005 was calculated to be $575.95.

The Federal per diem base rate has been updated in accordance with applicable statutory requirements and § 412.428 through publication of annual notices or proposed and final rules. A detailed discussion on the standardized budget-neutral Federal per diem base rate and the electroconvulsive therapy (ECT) payment per treatment appears in the FY 2014 IPF PPS update notice (78 FR 46738 through 46740). These documents are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html.*

IPFs must include a valid procedure code for ECT services provided to IPF beneficiaries in order to bill for ECT services, as described in our Medicare Claims Processing Manual, Chapter 3, Section 190.7.3 (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.*) There were no changes to the ECT procedure codes used on IPF claims as a result of the final update to the ICD–10–PCS code set for FY 2022. Addendum B to this final rule shows the ECT procedure codes for FY 2022 and is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

2. Final Update of the Federal Per Diem Base Rate and Electroconvulsive Therapy Payment per Treatment

The current (FY 2021) Federal per diem base rate is $815.22 and the ECT payment per treatment is $350.97. For the final FY 2022 Federal per diem base rate, we applied the payment rate update of 2.0 percent—that is, the 2016-based IPF market basket increase for FY 2022 of 2.7 percent less the productivity adjustment of 0.7 percentage point—and the wage index budget-neutrality factor of 1.0017 (as discussed in section III.D.1 of this final rule) to the FY 2021 Federal per diem base rate of $815.22, yielding a final Federal per diem base rate of $832.94 for FY 2022. Similarly, we applied the 2.0 percent payment rate update and the 1.0017 wage index budget-neutrality factor to the FY 2021 ECT payment per treatment of $350.97, yielding a final ECT payment per treatment of $358.60 for FY 2022.

Section 1886(s)(4)(A)(i) of the Act requires that for RY 2014 and each subsequent RY, in the case of an IPF that fails to report required quality data with respect to such RY, the Secretary will reduce any annual update to a standard Federal rate for discharges during the RY by 2.0 percentage points. Therefore, we are applying a 2.0 percentage point reduction to the Federal per diem base rate and the ECT payment per treatment as follows:

- For IPFs that fail requirements under the IPFQR Program, we applied a 0.0 percent payment rate update—that is, the IPF market basket increase for FY 2022 of 2.7 percent less the productivity adjustment of 0.7 percentage point for an update of 2.0 percent, and further reduced by 2 percentage points in accordance with section 1886(s)(4)(A)(i) of the Act—and the wage index budget-neutrality factor of 1.0017 to the FY 2021 Federal per diem base rate of $815.22, yielding a Federal per diem base rate of $816.61 for FY 2022.
- For IPFs that fail to meet requirements under the IPFQR Program, we applied the 0.0 percent annual payment rate update and the 1.0017 wage index budget-neutrality factor to the FY 2021 ECT payment per treatment of $350.97, yielding an ECT payment per treatment of $351.57 for FY 2022.

C. Final Updates to the IPF PPS Patient-Level Adjustment Factors

1. Overview of the IPF PPS Adjustment Factors

The IPF PPS payment adjustments were derived from a regression analysis of 100 percent of the FY 2002 Medicare Provider and Analysis Review (MedPAR) data file, which contained 483,038 cases. For a more detailed description of the data file used for the regression analysis, see the November 2004 IPF PPS final rule (69 FR 66935 through 66936). We are finalizing our proposal to continue to use the existing regression-derived adjustment factors established in 2005 for FY 2022. However, we have used more recent claims data to simulate payments to finalize the outlier fixed dollar loss threshold amount and to assess the impact of the IPF PPS updates.

2. IPF PPS Patient-Level Adjustments

The IPF PPS includes payment adjustments for the following patient-level characteristics: Medicare Severity Diagnosis Related Groups (MS–DRGs) assignment of the patient's principal diagnosis, selected comorbidities, patient age, and the variable per diem adjustments.

a. Final Update to MS–DRG Assignment

We believe it is important to maintain for IPFs the same diagnostic coding and Diagnosis Related Group (DRG) classification used under the IPPS for providing psychiatric care. For this reason, when the IPF PPS was implemented for cost reporting periods beginning on or after January 1, 2005, we adopted the same diagnostic code set (ICD–9–CM) and DRG patient classification system (MS–DRGs) that were utilized at the time under the IPPS. In the RY 2009 IPF PPS notice (73 FR 25709), we discussed CMS' effort to better recognize resource use and the severity of illness among patients. CMS adopted the new MS–DRGs for the IPPS in the FY 2008 IPPS final rule with comment period (72 FR 47130). In the RY 2009 IPF PPS notice (73 FR 25716), we provided a crosswalk to reflect changes that were made under the IPF PPS to adopt the new MS–DRGs. For a detailed description of the mapping changes from the original DRG adjustment categories to the current MS–DRG adjustment categories, we refer readers to the RY 2009 IPF PPS notice (73 FR 25714).

The IPF PPS includes payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient's principal diagnosis. The DRG adjustment factors were expressed relative to the most frequently reported psychiatric DRG in FY 2002, that is, DRG 430 (psychoses). The coefficient values and adjustment factors were derived from the regression analysis discussed in detail in the November 28, 2003 IPF proposed rule (68 FR 66923; 66928 through 66933) and the November 15, 2004 IPF final rule (69 FR 66933 through 66960). Mapping the DRGs to the MS–DRGs resulted in the current 17 IPF MS–DRGs, instead of the original 15 DRGs, for which the IPF PPS provides an adjustment. For FY 2022, we did not propose any changes to the IPF MSDRG adjustment factors. Therefore, we are finalizing our proposal to maintain the existing IPF MS–DRG adjustment factors.

In the FY 2015 IPF PPS final rule published August 6, 2014 in the **Federal Register** titled, ''Inpatient Psychiatric Facilities Prospective Payment System—Update for FY Beginning October 1, 2014 (FY 2015)'' (79 FR 45945 through 45947), we finalized conversions of the ICD–9–CM-based MS–DRGs to ICD–10–CM/PCS-based MS–DRGs, which were implemented on October 1, 2015. Further information on the ICD–10–CM/PCS MS–DRG conversion project can be found on the CMS ICD–10–CM website at *https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*.

For FY 2022, we are finalizing our proposal to continue to make the existing payment adjustment for psychiatric diagnoses that group to one of the existing 17 IPF MS–DRGs listed in Addendum A. Addendum A is available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html*. Psychiatric principal diagnoses that do not group to one of the 17 designated MS–DRGs will still receive the Federal per diem base rate and all other applicable adjustments, but the payment will not include an MS–DRG adjustment.

The diagnoses for each IPF MS–DRG will be updated as of October 1, 2021, using the final IPPS FY 2022 ICD–10–CM/PCS code sets. The FY 2022 IPPS/LTCH PPS final rule includes tables of the changes to the ICD–10–CM/PCS code sets, which underlie the FY 2022 IPF MS–DRGs. Both the FY 2022 IPPS final rule and the tables of final changes to the ICD–10–CM/PCS code sets, which underlie the FY 2022 MS–DRGs, are available on the CMS IPPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Code First

As discussed in the ICD–10–CM Official Guidelines for Coding and Reporting, certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the ICD–10–CM has a coding convention that requires the underlying condition be sequenced first followed by the manifestation. Wherever such a combination exists, there is a ''use additional code'' note at the etiology code, and a ''code first'' note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes (etiology followed by manifestation). In accordance with the ICD–10–CM Official Guidelines for Coding and Reporting, when a primary (psychiatric) diagnosis code has a ''code first'' note, the provider will follow the instructions in the ICD–10–CM Tabular List. The submitted claim goes through the CMS processing system, which will identify the principal diagnosis code as non-psychiatric and search the secondary codes for a psychiatric code to assign a DRG code for adjustment. The system will continue to search the secondary codes for those that are appropriate for comorbidity adjustment.

For more information on the code first policy, we refer our readers to the November 2004 IPF PPS final rule (69 FR 66945) and see sections I.A.13 and I.B.7 of the FY 2020 ICD–10–CM Coding Guidelines, available at *https://www.cdc.gov/nchs/data/icd/10cmguidelines-FY2020_final.pdf*. In the FY 2015 IPF PPS final rule, we provided a code first table for reference that highlights the same or similar manifestation codes where the code first instructions apply in ICD–10–CM that were present in ICD–9–CM (79 FR 46009). In FY 2018, FY 2019 and FY 2020, there were no changes to the final ICD–10–CM codes in the IPF Code First table. For FY 2021, there were 18 ICD–10–CM codes deleted from the final IPF Code First table. For FY 2022 there are 18 codes finalized for deletion from the ICD–10–CM codes in the IPF Code First table. The final FY 2022 Code First table is shown in Addendum B on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html*.

b. Final Payment for Comorbid Conditions

The intent of the comorbidity adjustments is to recognize the increased costs associated with comorbid conditions by providing additional payments for certain existing medical or psychiatric conditions that are expensive to treat. In our RY 2012 IPF PPS final rule (76 FR 26451 through 26452), we explained that the IPF PPS includes 17 comorbidity categories and identified the new, revised, and deleted ICD–9–CM diagnosis codes that generate a comorbid condition payment adjustment under the IPF PPS for RY 2012 (76 FR 26451).

Comorbidities are specific patient conditions that are secondary to the patient's principal diagnosis and that require treatment during the stay. Diagnoses that relate to an earlier episode of care and have no bearing on the current hospital stay are excluded and must not be reported on IPF claims. Comorbid conditions must exist at the time of admission or develop subsequently, and affect the treatment received, length of stay (LOS), or both treatment and LOS.

For each claim, an IPF may receive only one comorbidity adjustment within a comorbidity category, but it may receive an adjustment for more than one comorbidity category. Current billing instructions for discharge claims, on or after October 1, 2015, require IPFs to enter the complete ICD–10–CM codes for up to 24 additional diagnoses if they co-exist at the time of admission, or develop subsequently and impact the treatment provided.

The comorbidity adjustments were determined based on the regression analysis using the diagnoses reported by IPFs in FY 2002. The principal diagnoses were used to establish the DRG adjustments and were not accounted for in establishing the comorbidity category adjustments, except where ICD–9–CM code first instructions applied. In a code first situation, the submitted claim goes through the CMS processing system, which will identify the principal diagnosis code as non-psychiatric and search the secondary codes for a psychiatric code to assign an MS–DRG code for adjustment. The system will continue to search the secondary codes for those that are appropriate for comorbidity adjustment.

As noted previously, it is our policy to maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. The 17 comorbidity categories formerly defined using ICD–9–CM codes were converted to ICD–10–CM/PCS in our FY 2015 IPF PPS final rule (79 FR 45947 through 45955). The goal for converting the comorbidity categories is referred to as replication, meaning that the payment adjustment for a given patient encounter is the same after ICD–10–CM implementation as it will be if the same record had been coded in ICD–9–CM and submitted prior to ICD–10–CM/PCS implementation on October 1, 2015. All conversion efforts were made with the intent of achieving this goal. For FY 2022, we are finalizing our proposal to continue to use the same comorbidity adjustment factors in effect in FY 2021, which are found in Addendum A, available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html*.

We have updated the ICD–10–CM/PCS codes, which are associated with the existing IPF PPS comorbidity categories, based upon the final FY 2022 update to the ICD–10–CM/PCS code set. The final FY 2022 ICD–10–CM/PCS updates include: 8 ICD–10–CM diagnosis codes added to the Poisoning comorbidity category, 4 codes deleted, and 4 changes to Poisoning comorbidity long descriptions; 2 ICD–10–CM diagnosis codes added to the Developmental Disabilities comorbidity category and 1 code deleted; and 3 ICD–10–PCS codes added to the Oncology Procedures comorbidity category. These updates are detailed in Addenda B of this final rule, which are available on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html*.

In accordance with the policy established in the FY 2015 IPF PPS final rule (79 FR 45949 through 45952), we reviewed all new FY 2022 ICD–10–CM codes to remove codes that were site ''unspecified'' in terms of laterality from the FY 2022 ICD–10–CM/PCS codes in instances where more specific codes are available. As we stated in the FY 2015 IPF PPS final rule, we believe that specific diagnosis codes that narrowly identify anatomical sites where disease, injury, or a condition exists should be used when coding patients' diagnoses whenever these codes are available. We finalized in the FY 2015 IPF PPS rule, that we would remove site ''unspecified'' codes from the IPF PPS ICD–10–CM/PCS codes in instances when laterality codes (site specified codes) are available, as the clinician should be able to identify a more specific diagnosis based on clinical assessment at the medical encounter. None of the finalized additions to the FY 2022 ICD–10–CM/PCS codes were site ''unspecified'' by laterality, therefore, we are not removing any of the new codes.

Comment: A commenter requested that CMS add 13 ICD–10–CM codes for infectious diseases to the list of codes that qualify for the IPF PPS comorbidity adjustment.

Response: As noted previously, the intent of the comorbidity adjustments is to recognize the increased costs associated with comorbid conditions by providing additional payments for certain existing medical or psychiatric conditions that are expensive to treat. Also, the comorbidity adjustments were derived through a regression analysis, which also includes other IPF PPS adjustments (for example, the age adjustment). Our established policy is to annually update the ICD–10–CM/PCS codes, which are associated with the existing IPF PPS comorbidity categories. Adding or removing codes to the existing comorbidity categories that are not part of the annual coding update would occur as part of a larger IPF PPS refinement. We did not propose to refine the IPF PPS in the FY 2022 IPF PPS proposed rule, and therefore, are not changing the policy in this final rule. However, we will consider the comment to potentially inform future refinements.

c. Final Patient Age Adjustments

As explained in the November 2004 IPF PPS final rule (69 FR 66922), we analyzed the impact of age on per diem cost by examining the age variable (range of ages) for payment adjustments. In general, we found that the cost per day increases with age. The older age groups are costlier than the under 45 age group, the differences in per diem cost increase for each successive age group, and the differences are statistically significant. For FY 2022, we are finalizing our proposal to continue to use the patient age adjustments currently in effect in FY 2021, as shown in Addendum A of this rule (see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html*).

d. Final Variable Per Diem Adjustments

We explained in the November 2004 IPF PPS final rule (69 FR 66946) that the regression analysis indicated that per diem cost declines as the length of stay (LOS) increases. The variable per diem adjustments to the Federal per diem base rate account for ancillary and administrative costs that occur disproportionately in the first days after admission to an IPF. As discussed in the November 2004 IPF PPS final rule, we used a regression analysis to estimate the average differences in per diem cost among stays of different lengths (69 FR 66947 through 66950). As a result of this analysis, we established variable per diem adjustments that begin on day 1 and decline gradually until day 21 of a patient's stay. For day 22 and thereafter, the variable per diem adjustment remains the same each day for the remainder of the stay. However, the adjustment applied to day 1 depends upon whether the IPF has a qualifying ED. If an IPF has a qualifying ED, it receives a 1.31 adjustment factor for day 1 of each stay. If an IPF does not have a qualifying ED, it receives a 1.19 adjustment factor for day 1 of the stay. The ED adjustment is explained in more detail in section III.D.4 of this rule.

For FY 2022, we are finalizing our proposal to continue to use the variable per diem adjustment factors currently in effect, as shown in Addendum A of this rule (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html*). A complete discussion of the variable per diem adjustments appears in the November 2004 IPF PPS final rule (69 FR 66946).

D. Final Updates to the IPF PPS Facility-Level Adjustments

The IPF PPS includes facility-level adjustments for the wage index, IPFs located in rural areas, teaching IPFs, cost of living adjustments for IPFs located in Alaska and Hawaii, and IPFs with a qualifying ED.

1. Wage Index Adjustment

a. Background

As discussed in the RY 2007 IPF PPS final rule (71 FR 27061), RY 2009 IPF PPS (73 FR 25719) and the RY 2010 IPF PPS notices (74 FR 20373), in order to provide an adjustment for geographic wage levels, the labor-related portion of an IPF's payment is adjusted using an appropriate wage index. Currently, an IPF's geographic wage index value is determined based on the actual location of the IPF in an urban or rural area, as defined in § 412.64(b)(1)(ii)(A) and (C).

Due to the variation in costs and because of the differences in geographic wage levels, in the November 15, 2004 IPF PPS final rule, we required that payment rates under the IPF PPS be adjusted by a geographic wage index. We proposed and finalized a policy to use the unadjusted, pre-floor, pre-reclassified IPPS hospital wage index to account for geographic differences in IPF labor costs. We implemented use of the pre-floor, pre-reclassified IPPS hospital wage data to compute the IPF wage index since there was not an IPF-specific wage index available. We believe that IPFs generally compete in the same labor market as IPPS hospitals so the pre-floor, pre-reclassified IPPS hospital wage data should be reflective of labor costs of IPFs. We believe this pre-floor, pre-reclassified IPPS hospital wage index to be the best available data to use as proxy for an IPF specific wage index. As discussed in the RY 2007 IPF PPS final rule (71 FR 27061 through 27067), under the IPF PPS, the wage index is calculated using the IPPS wage index for the labor market area in which the IPF is located, without considering geographic reclassifications, floors, and other adjustments made to the wage index under the IPPS. For a complete description of these IPPS wage index adjustments, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41390). Our wage index policy at § 412.424(a)(2), requires us to use the best Medicare data available to estimate costs per day, including an appropriate wage index to adjust for wage differences.

When the IPF PPS was implemented in the November 15, 2004 IPF PPS final rule, with an effective date of January 1, 2005, the pre-floor, pre-reclassified IPPS hospital wage index that was available at the time was the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index. Historically, the IPF wage index for a given RY has used the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY as its basis. This has been due in part to the pre-floor, pre-reclassified IPPS hospital wage index data that were available during the IPF rulemaking cycle, where an annual IPF notice or IPF final rule was usually published in early May. This publication timeframe was relatively early compared to other Medicare payment rules because the IPF PPS follows a RY, which was defined in the implementation of the IPF PPS as the 12-month period from July 1 to June 30 (69 FR 66927). Therefore, the best available data at the time the IPF PPS was implemented was the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY (for example, the RY 2006 IPF wage index was based on the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index).

In the RY 2012 IPF PPS final rule, we changed the reporting year timeframe for IPFs from a RY to the FY, which begins October 1 and ends September 30 (76 FR 26434 through 26435). In that FY 2012 IPF PPS final rule, we continued our established policy of using the pre-floor, pre-reclassified IPPS hospital wage index from the prior year (that is, from FY 2011) as the basis for the FY 2012 IPF wage index. This policy of basing a wage index on the prior year's pre-floor, pre-reclassified IPPS hospital wage index has been followed by other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. By continuing with our established policy, we remained consistent with other Medicare payment systems.

In FY 2020, we finalized the IPF wage index methodology to align the IPF PPS wage index with the same wage data timeframe used by the IPPS for FY 2020 and subsequent years. Specifically, we finalized to use the pre-floor, pre-reclassified IPPS hospital wage index from the FY concurrent with the IPF FY as the basis for the IPF wage index. For example, the FY 2020 IPF wage index was based on the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index rather than on the FY 2019 pre-floor, pre-reclassified IPPS hospital wage index.

We explained in the FY 2020 proposed rule (84 FR 16973), that using the concurrent pre-floor, pre-reclassified IPPS hospital wage index will result in the most up-to-date wage data being the basis for the IPF wage index. It will also result in more consistency and parity in the wage index methodology used by other Medicare payment systems. The Medicare SNF PPS already used the concurrent IPPS hospital wage index data as the basis for the SNF PPS wage index. Thus, the wage adjusted Medicare payments of various provider types will be based upon wage index data from the same timeframe. CMS proposed similar policies to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index data in other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. For FY 2022, we proposed to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

Comment: Several commenters expressed concerns with our proposal to continue using the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index. Three commenters recommended CMS extend the transition for the reductions in payment for certain IPFs resulting from the wage index changes adopted in the FY 2021 IPF PPS final rule. Another commenter also recommended that CMS apply a non-budget neutral 5 percent cap on decreases to a hospital's wage index value to help mitigate wide annual swings that are beyond a hospital's ability to control.

Response: We did not propose to modify the transition policy that was finalized in the FY 2021 IPF PPS final rule; therefore, we are not changing the previously adopted policy in this final rule. As we discussed in the FY 2021 IPF PPS final rule (85 FR 47058 through 47059), the transition policy caps the estimated reduction in an IPF's wage index to 5 percent in FY 2021, with no cap applied in FY 2022. We stated our belief that implementing updated wage index values along with the revised OMB delineations will result in wage index values being more representative of the actual costs of labor in a given area. As evidenced by the detailed economic analysis (85 FR 47065 through 47068), we estimated that implementing these wage index changes would have distributional effects, both positive and negative, among IPF providers. We continue to believe that applying the 5-percent cap transition policy in year one provided an adequate safeguard against any significant payment reductions, has allowed for sufficient time to make operational changes for future FYs, and provided a reasonable balance between mitigating some short-term instability in IPF payments and improving the accuracy of the payment adjustment for differences in area wage levels.

We note that certain changes to wage index policy may significantly affect Medicare payments. These changes may arise from revisions to the OMB delineations of statistical areas resulting from the decennial census data, periodic updates to the OMB delineations in the years between the decennial censuses, or other wage index policy changes. While we consider how best to address these potential scenarios in a consistent and thoughtful manner, we reiterate that our policy principles with regard to the wage index include generally using the most current data and information available and providing that data and information, as well as any approaches to addressing any significant effects on Medicare payments resulting from these potential scenarios, in notice and comment rulemaking.

Comment: Two commenters recommended that CMS incorporate a frontier state floor into the IPF wage index. Another commenter requested that CMS implement policies to address the disparity in payments between rural and urban IPFs, similar to policies that have been adopted for IPPS hospitals.

Response: We appreciate commenters' suggestions regarding opportunities to improve the accuracy of the IPF wage index. We did not propose the specific policies that commenters have suggested, but we will take them into consideration to potentially inform future rulemaking.

Final Decision: For FY 2022, we are finalizing the proposal to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index. Since we did not propose any changes to the 2-year transition that was finalized in the FY 2021 IPF PPS final rule, there will be no cap applied to the reduction in the wage index for the second year (that is, FY 2022).

We will apply the IPF wage index adjustment to the labor-related share of the national base rate and ECT payment per treatment. The labor-related share of the national rate and ECT payment per treatment will change from 77.3 percent in FY 2021 to 77.2 percent in FY 2022. This percentage reflects the labor-related share of the 2016-based IPF market basket for FY 2022 (see section III.A.4 of this rule).

b. Office of Management and Budget (OMB) Bulletins

(i.) Background

The wage index used for the IPF PPS is calculated using the unadjusted, pre-reclassified and pre-floor IPPS wage index data and is assigned to the IPF on the basis of the labor market area in which the IPF is geographically located. IPF labor market areas are delineated based on the Core-Based Statistical Area (CBSAs) established by the OMB.

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 through OMB Bulletins. These bulletins contain information regarding CBSA changes, including changes to CBSA numbers and titles. OMB bulletins may be accessed online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/*. In accordance with our established methodology, the IPF PPS has historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the IPPS hospital wage index used to determine the IPF wage index and, when necessary and appropriate, has proposed and finalized transition policies for these changes.

In the RY 2007 IPF PPS final rule (71 FR 27061 through 27067), we adopted the changes discussed in the OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for MSAs, and the creation of Micropolitan Statistical Areas and Combined Statistical Areas. In adopting the OMB CBSA geographic designations in RY 2007, we did not provide a separate transition for the CBSA-based wage index since the IPF PPS was already in a transition period from TEFRA payments to PPS payments.

In the RY 2009 IPF PPS notice, we incorporated the CBSA nomenclature changes published in the most recent OMB bulletin that applied to the IPPS hospital wage index used to determine the current IPF wage index and stated that we expected to continue to do the same for all the OMB CBSA nomenclature changes in future IPF PPS rules and notices, as necessary (73 FR 25721).

Subsequently, CMS adopted the changes that were published in past OMB bulletins in the FY 2016 IPF PPS final rule (80 FR 46682 through 46689), the FY 2018 IPF PPS rate update (82 FR 36778 through 36779), the FY 2020 IPF PPS final rule (84 FR 38453 through 38454), and the FY 2021 IPF PPS final rule (85 FR 47051 through 47059). We direct readers to each of these rules for more information about the changes that were adopted and any associated transition policies.

In part due to the scope of changes involved in adopting the CBSA delineations for FY 2021, we finalized a 2-year transition policy consistent with our past practice of using transition policies to help mitigate negative impacts on hospitals of certain wage index policy changes. We applied a 5-percent cap on wage index decreases to all IPF providers that had any decrease in their wage indexes, regardless of the circumstance causing the decline, so that an IPF's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020, regardless of whether the IPF was part of an updated CBSA. We refer readers to the FY 2021 IPF PPS final rule (85 FR 47058 through 47059) for a more detailed discussion about the wage index transition policy for FY 2021.

On March 6, 2020 OMB issued OMB Bulletin 20–01 (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). In considering whether to adopt this bulletin, we analyzed whether the changes in this bulletin would have a material impact on the IPF PPS wage index. This bulletin creates only one Micropolitan statistical area. As discussed in further detail in section III.D.1.b.ii, since Micropolitan areas are considered rural for the IPF PPS wage index, this bulletin has no material impact on the IPF PPS wage index. That is, the constituent county of the new Micropolitan area was considered rural effective as of FY 2021 and would continue to be considered rural if we adopted OMB Bulletin 20–01. Therefore, we did not propose to adopt OMB Bulletin 20–01 in the FY 2022 IPF PPS proposed rule.

(ii.) Micropolitan Statistical Areas

OMB defines a ''Micropolitan Statistical Area'' as a CBSA associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), we determined the best course of action would be to treat Micropolitan Areas as ''rural'' and include them in the calculation of each state's IPF PPS rural wage index. We refer the reader to the FY 2007 IPF PPS final rule (71 FR 27064 through 27065) for a complete discussion regarding treating Micropolitan Areas as rural.

c. Final Adjustment for Rural Location

In the November 2004 IPF PPS final rule, (69 FR 66954) we provided a 17 percent payment adjustment for IPFs located in a rural area. This adjustment was based on the regression analysis, which indicated that the per diem cost

of rural facilities was 17 percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. This 17 percent adjustment has been part of the IPF PPS each year since the inception of the IPF PPS. For FY 2022, we proposed to continue to apply a 17 percent payment adjustment for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C) (see 69 FR 66954 for a complete discussion of the adjustment for rural locations).

Comment: We received one comment in favor of the proposed extension of the 17 percent payment adjustment for rural IPFs. The commenter acknowledged CMS' efforts to avoid disparities in payments to facilities in rural and underserved communities.

Response: We appreciate this comment of support. Since the inception of the IPF PPS, we have applied a 17 percent adjustment for IPFs located in rural areas. As stated in the previous paragraph, this adjustment was derived from the results of our regression analysis and was incorporated into the payment system in order to ensure the accuracy of payments to rural IPFs. CMS continues to look for ways to ensure accuracy of payments to rural IPFs.

Final Decision: For FY 2022, we are finalizing our proposal to continue to apply a 17 percent payment adjustment for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C).

d. Final Budget Neutrality Adjustment

Changes to the wage index are made in a budget-neutral manner so that updates do not increase expenditures. Therefore, for FY 2022, we are finalizing our proposal to continue to apply a budget-neutrality adjustment in accordance with our existing budget-neutrality policy. This policy requires us to update the wage index in such a way that total estimated payments to IPFs for FY 2022 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the IPF PPS rates. We use the following steps to ensure that the rates reflect the FY 2022 update to the wage indexes (based on the FY 2018 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1: Simulate estimated IPF PPS payments, using the FY 2021 IPF wage index values (available on the CMS website) and labor-related share (as published in the FY 2021 IPF PPS final rule (85 FR 47043)).

Step 2: Simulate estimated IPF PPS payments using the final FY 2022 IPF wage index values (available on the CMS website) and final FY 2022 labor-related share (based on the latest available data as discussed previously).

Step 3: Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2022 budget-neutral wage adjustment factor of 1.0017.

Step 4: Apply the FY 2022 budget-neutral wage adjustment factor from step 3 to the FY 2021 IPF PPS Federal per diem base rate after the application of the market basket update described in section III.A of this rule, to determine the FY 2022 IPF PPS Federal per diem base rate.

2. Final Teaching Adjustment

a. Background

In the November 2004 IPF PPS final rule, we implemented regulations at sect; 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The teaching adjustment accounts for the higher indirect operating costs experienced by hospitals that participate in graduate medical education (GME) programs. The payment adjustments are made based on the ratio of the number of full-time equivalent (FTE) interns and residents training in the IPF and the IPF's average daily census (ADC).

Medicare makes direct GME payments (for direct costs such as resident and teaching physician salaries, and other direct teaching costs) to all teaching hospitals including those paid under a PPS, and those paid under the TEFRA rate-of-increase limits. These direct GME payments are made separately from payments for hospital operating costs and are not part of the IPF PPS. The direct GME payments do not address the estimated higher indirect operating costs teaching hospitals may face.

The results of the regression analysis of FY 2002 IPF data established the basis for the payment adjustments included in the November 2004 IPF PPS final rule. The results showed that the indirect teaching cost variable is significant in explaining the higher costs of IPFs that have teaching programs. We calculated the teaching adjustment based on the IPF's ''teaching variable,'' which is (1 + (the number of FTE residents training in the IPF/the IPF's ADC)). The teaching variable is then raised to the 0.5150 power to result in the teaching adjustment. This formula is subject to the limitations on the number of FTE residents, which are described in this section of this rule.

We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching adjustment. The cap limits the number of FTE residents that teaching IPFs may count for the purpose of calculating the IPF PPS teaching adjustment, not the number of residents teaching institutions can hire or train. We calculated the number of FTE residents that trained in the IPF during a ''base year'' and used that FTE resident number as the cap. An IPF's FTE resident cap is ultimately determined based on the final settlement of the IPF's most recent cost report filed before November 15, 2004 (publication date of the IPF PPS final rule). A complete discussion of the temporary adjustment to the FTE cap to reflect residents due to hospital closure or residency program closure appears in the RY 2012 IPF PPS proposed rule (76 FR 5018 through 5020) and the RY 2012 IPF PPS final rule (76 FR 26453 through 26456). In section III.D.2.b of this final rule, we discuss finalized updates to the IPF policy on temporary adjustment to the FTE cap.

In the regression analysis, the logarithm of the teaching variable had a coefficient value of 0.5150. We converted this cost effect to a teaching payment adjustment by treating the regression coefficient as an exponent and raising the teaching variable to a power equal to the coefficient value. We note that the coefficient value of 0.5150 was based on the regression analysis holding all other components of the payment system constant. A complete discussion of how the teaching adjustment was calculated appears in the November 2004 IPF PPS final rule (69 FR 66954 through 66957) and the RY 2009 IPF PPS notice (73 FR 25721). As with other adjustment factors derived through the regression analysis, we do not plan to rerun the teaching adjustment factors in the regression analysis until we more fully analyze IPF PPS data. Therefore, in this FY 2022 final rule, we are finalizing our proposal to continue to retain the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate.

b. Final Update to IPF Teaching Policy on IPF Program Closures and Displaced Residents

For FY 2022, we proposed to change the IPF policy regarding displaced residents from IPF closures and closures of IPF teaching programs. Specifically, we proposed to adopt conforming changes to the IPF PPS teaching policy

to align with the policy changes that the IPPS finalized in the FY 2021 IPPS final rule (85 FR 58865 through 58870). We believe that the IPF IME policy relating to hospital closure and displaced students is susceptible to the same vulnerabilities as IPPS GME policy. Hence, if an IPF with a large number of residents training in its residency program announces that it is closing, these residents will become displaced and will need to find alternative positions at other IPF hospitals or risk being unable to become Board-certified. Although we proposed to adopt a policy under the IPF PPS that is consistent with an applicable policy under the IPPS, the actual caps under the two payment systems may not be commingled. In other words, the resident cap applicable under the IPPS is separate from the resident cap applicable under the IPF PPS; moreover, a provider cannot add its IPF resident cap to its IPPS resident cap in order to increase the number of residents it receives payment for under either payment system.

As stated in the November 2004 IPF PPS final rule (69 FR 66922), we implemented regulations at § 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The facility-level adjustment we are providing for teaching hospitals under IPF PPS parallels the IME payments paid under the IPPS. Both payments are add on adjustments to the amount per case and both are based in part on the number of full-time equivalent (FTE) residents training at the facility.

The regulation at 42 CFR 412.424(d)(1)(iii)(F) permits an IPF to temporarily adjust its FTE cap to reflect residents added because of another hospital or program's closure. We first implemented regulations regarding residents displaced by teaching hospital and program closures in the May 6, 2011 IPF PPS final rule (76 FR 26431). In that final rule, we adopted the IPPS definition of ''closure of a hospital'' at 42 CFR 413.79(h)(1)(i) to apply to IPF closures as well, and to mean that the IPF terminates its Medicare provider agreement as specified in 42 CFR 489.52. In the proposed rule, we proposed to codify this definition, as well as, the definition of an IPF program closure, at § 412.402.

Although not explicitly stated in regulatory text, our current policy is that a displaced resident is one that is physically present at the hospital training on the day prior to or the day of hospital or program closure. This longstanding policy derived from the fact that in the regulations text, there are requirements that the receiving hospital identifies the residents ''who have come from the closed IPF'' (§ 412.424(d)(1)(iii)(F)(*1*)(*ii*)) or identifies the residents ''who have come from another IPF's closed program'' (§ 412.424(d)(1)(iii)(F)(*2*)(*i*)), and that the IPF that closed its program identifies ''the residents who were in training at the time of the program's closure'' (§ 412.424(d)(1)(iii)(F)(*2*)(*ii*)). We considered the residents who were physically present at the IPF to be those residents who were ''training at the time of the program's closure,'' thereby granting them the status of ''displaced residents.'' Although we did not want to limit the ''displaced residents'' to only those physically present at the time of closure, it becomes much more administratively challenging for the following groups of residents at closing IPFs/programs to continue their training: (1) Residents who leave the program after the closure is publicly announced to continue training at another IPF, but before the actual closure; (2) residents assigned to and training at planned rotations at other IPFs who will be unable to return to their rotations at the closing IPF or program; and (3) individuals (such as medical students or would-be fellows) who matched into resident programs at the closing IPF or program but have not yet started training at the closing IPF or program. Other groups of residents who, under current policy, are already considered ''displaced residents'' include—(1) residents who are physically training in the IPF on the day prior to or day of program or IPF closure; and (2) residents who would have been at the closing IPF or IPF program on the day prior to or of closure but were on approved leave at that time, and are unable to return to their training at the closing IPF or IPF program.

We proposed to amend the IPF policy with regard to closing teaching IPFs and closing residency programs to address the needs of residents attempting to find alternative IPFs in which to complete their training. Additionally, this proposal addresses the incentives of originating and receiving IPFs with regard to ensuring we appropriately account for their indirect teaching costs by way of an appropriate IPF teaching adjustment based on each program's resident FTEs. We proposed to change two aspects of the current IPF policy, which are discussed in the following section.

First, rather than link the status of displaced residents, for the purpose of the receiving IPF's request to increase their FTE cap, to the resident's presence at the closing IPF or program on the day prior to or the day of program or IPF closure, we proposed that the ideal day will be the day that the closure was publicly announced, (for example, via a press release or a formal notice to the Accreditation Council on Graduate Medical Education (ACGME)). This will provide greater flexibility for the residents to transfer while the IPF operations or residency programs were winding down, rather than waiting until the last day of IPF or program operation. This will address the needs of the first group of residents as previously described: Residents who leave the IPF program after the closure was publicly announced to continue training at another IPF, but before the day of actual closure.

Second, by removing the link between the status of displaced residents and their presence at the closing IPF or program on the day prior to or the day of program or IPF closure, we proposed to also allow the second and third group of residents who are not physically at the closing IPF/closing program, but had intended to train at (or return to training at, in the case of residents on rotation) to be considered displaced residents. Thus, we proposed to revise our teaching policy with regard to which residents can be considered ''displaced'' for the purpose of the receiving IPF's request to increase their FTE cap in the situation where an IPF announces publicly that it is closing or that it is closing an IPF residency program(s). Specifically, we are adopting the definitions of ''closure of a hospital'', ''closure of a hospital residency training program'', and ''displaced resident'' as defined at 42 CFR 413.79(h) but with respect to IPFs and for the purposes of accounting for indirect teaching costs.

In addition, we proposed to change another detail of the IPF teaching policy specific to the requirements for the receiving IPF. To apply for the temporary increase in the FTE resident cap, the receiving IPF will have to submit a letter to its Medicare Administrative Contractor (MAC) within 60 days of beginning the training of the displaced residents. As established under existing regulation at § 412.424(d)(1)(iii)(F)(*1*)(*ii*) and § 412.424(d)(1)(iii)(F)(*2*)(*i*), this letter must identify the residents who have come from the closed IPF or program that have caused the receiving IPF to exceed its cap, and the receiving IPF must specify the length of time the adjustment is needed. Moreover, we want to propose clarifications on how the information will be delivered in this letter. Consistent with IPPS teaching policy, we proposed that the letter from the receiving IPF will have to include:

(1) The name of each displaced resident; (2) the last four digits of each displaced resident's social security number; (3) the IPF and program in which each resident was training previously; and (4) the amount of the cap increase needed for each resident (based on how much the receiving IPF is in excess of its cap and the length of time for which the adjustments are needed). We proposed to require the receiving hospital to only supply the last four digits of each displaced resident's social security number to reduce the amount of personally identifiable information (PII) included in these agreements.

We also clarified, as previously discussed in the May 6, 2011 IPF PPS final rule (76 FR 26455), the maximum number of FTE resident cap slots that could be transferred to all receiving IPFs is the number of FTE resident cap slots belonging to the IPF that has the closed program or that is closing. Therefore, if the originating IPF is training residents in excess of its cap, then being a displaced resident does not guarantee that a cap slot will be transferred along with that resident. Therefore, if there are more IPF displaced residents than available cap slots, the slots may be apportioned according to the closing IPF's discretion. The decision to transfer a cap slot if one is available will be voluntary and made at the sole discretion of the originating IPF. However, if the originating IPF decides to do so, then it will be the originating IPF's responsibility to determine how much of an available cap slot will go with a particular resident (if any). We also note, as we previously discussed in the May 6, 2011 IPF PPS final rule (76 FR 25455), only to the extent a receiving IPF would exceed its FTE cap by training displaced residents would it be eligible for a temporary adjustment to its resident FTE cap. Displaced residents are factored into the receiving IPF's ratio of resident FTEs to the facility's average daily census.

Comment: We received 3 comments on our proposed updates to IPF teaching policy. All commenters appreciate the alignment of IPF teaching policy with IPPS. They believe it is important to protect medical education. Therefore, decreasing confusion and streamlining the process gives residents and program directors more time to find a new program or rotation site, which can only help the transfer process.

Response: We thank these commenters for their support.

Final Decision: For FY 2022, we are finalizing the closure policy as proposed. Section 124 of the BBRA gives the Secretary broad discretion to determine the appropriate adjustment factors for the IPF PPS. We are finalizing our proposal to implement the policy regarding IPF resident caps and closures to remain consistent with the way that the IPPS teaching policy calculates FTE resident caps in the case of a receiving hospital that obtains a temporary IME and direct GME cap adjustment for assuming the training of displaced residents due to another hospital or residency program's closure. We are also finalizing our proposal that in the future, we will deviate from IPPS teaching policy as it pertains to counting displaced residents for the purposes of the IPF teaching adjustment only when it is necessary and appropriate for the IPF PPS.

In addition, we are finalizing our proposal to amend the IPF policy with regard to closing teaching IPFs and closing residency programs to address the needs of residents attempting to find alternative IPFs in which to complete their training. This proposal addresses the incentives of originating and receiving IPFs with regard to ensuring we appropriately account for their indirect teaching costs by way of an appropriate IPF teaching adjustment based on each program's resident FTEs. We are also finalizing our proposal to change two aspects of the current IPF policy, which are discussed in the following section.

First, rather than link the status of displaced residents for the purpose of the receiving IPF's request to increase their FTE cap to the resident's presence at the closing IPF or program on the day prior to or the day of program or IPF closure, we are finalizing our proposal that the ideal day will be the day that the closure was publicly announced, (for example, via a press release or a formal notice to the Accreditation Council on Graduate Medical Education (ACGME)). This will provide greater flexibility for the residents to transfer while the IPF operations or residency programs were winding down, rather than waiting until the last day of IPF or program operation. This will address the needs of the first group of residents as previously described: Residents who leave the IPF program after the closure was publicly announced to continue training at another IPF, but before the day of actual closure.

Second, by removing the link between the status of displaced residents and their presence at the closing IPF or program on the day prior to or the day of program or IPF closure, we are finalizing to also allow the second and third group of residents who are not physically at the closing IPF/closing program, but had intended to train at (or return to training at, in the case of residents on rotation) to be considered a displaced resident. Thus, we are finalizing our proposal to revise our teaching policy with regard to which residents can be considered ''displaced'' for the purpose of the receiving IPF's request to increase their FTE cap in the situation where an IPF announces publicly that it is closing or that it is closing an IPF residency program(s). Specifically, we are adopting the definitions of ''closure of a hospital'', ''closure of a hospital residency training program'', and ''displaced resident'' as defined at 42 CFR 413.79(h) but with respect to IPFs and for the purposes of accounting for indirect teaching costs.

In addition, we are finalizing our proposal to change another detail of the IPF teaching policy specific to the requirements for the receiving IPF. To apply for the temporary increase in the FTE resident cap, the receiving IPF will have to submit a letter to its Medicare Administrative Contractor (MAC) within 60 days of beginning the training of the displaced residents. As established under existing regulation at § 412.424(d)(1)(iii)(F)(*1*)(*ii*) and § 412.424(d)(1)(iii)(F)(*2*)(*i*), this letter must identify the residents who have come from the closed IPF or program that have caused the receiving IPF to exceed its cap, and the receiving IPF must specify the length of time the adjustment is needed. Moreover, we are finalizing the clarifications on how the information will be delivered in this letter. Consistent with IPPS teaching policy, the letter from the receiving IPF will have to include: (1) The name of each displaced resident; (2) the last four digits of each displaced resident's social security number; (3) the IPF and program in which each resident was training previously; and (4) the amount of the cap increase needed for each resident (based on how much the receiving IPF is in excess of its cap and the length of time for which the adjustments are needed). We are also finalizing our proposal to require the receiving hospital to only supply the last four digits of each displaced resident's social security number to reduce the amount of personally identifiable information (PII) included in these agreements.

We are also finalizing the clarification that the maximum number of FTE resident cap slots that could be transferred to all receiving IPFs is the number of FTE resident cap slots belonging to the IPF that has the closed program or that is closing. Therefore, if the originating IPF is training residents in excess of its cap, then being a displaced resident does not guarantee that a cap slot will be transferred along

with that resident. Therefore, if there are more IPF displaced residents than available cap slots, the slots may be apportioned according to the closing IPF's discretion. The decision to transfer a cap slot if one is available will be voluntary and made at the sole discretion of the originating IPF. However, if the originating IPF decides to do so, then it will be the originating IPF's responsibility to determine how much of an available cap slot will go with a particular resident (if any). We also note that, as we previously discussed in the May 6, 2011 IPF PPS final rule (76 FR 25455), only to the extent a receiving IPF would exceed its FTE cap by training displaced residents would it be eligible for a temporary adjustment to its resident FTE cap. Displaced residents are factored into the receiving IPF's ratio of resident FTEs to the facility's average daily census.

3. Final Cost of Living Adjustment for IPFs Located in Alaska and Hawaii

The IPF PPS includes a payment adjustment for IPFs located in Alaska and Hawaii based upon the area in which the IPF is located. As we explained in the November 2004 IPF PPS final rule, the FY 2002 data demonstrated that IPFs in Alaska and Hawaii had per diem costs that were disproportionately higher than other IPFs. Other Medicare prospective payment systems (for example, the IPPS and LTCH PPS) adopted a COLA to account for the cost differential of care furnished in Alaska and Hawaii.

We analyzed the effect of applying a COLA to payments for IPFs located in Alaska and Hawaii. The results of our analysis demonstrated that a COLA for IPFs located in Alaska and Hawaii will improve payment equity for these facilities. As a result of this analysis, we provided a COLA in the November 2004 IPF PPS final rule.

A COLA for IPFs located in Alaska and Hawaii is made by multiplying the non-labor-related portion of the Federal per diem base rate by the applicable COLA factor based on the COLA area in which the IPF is located.

The COLA factors through 2009 were published by the Office of Personnel Management (OPM), and the OPM memo showing the 2009 COLA factors is available at *https://www.chcoc.gov/content/nonforeign-area-retirement-equity-assurance-act.*

We note that the COLA areas for Alaska are not defined by county as are the COLA areas for Hawaii. In 5 CFR 591.207, the OPM established the following COLA areas:

- City of Anchorage, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse.
- City of Fairbanks, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse.
- City of Juneau, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse.
- Rest of the state of Alaska.

As stated in the November 2004 IPF PPS final rule, we update the COLA factors according to updates established by the OPM. However, sections 1911 through 1919 of the Non-foreign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for FY 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of NDAA, locality pay was phased in over a 3-year period beginning in January 2010, with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay.

When we published the proposed COLA factors in the RY 2012 IPF PPS proposed rule (76 FR 4998), we inadvertently selected the FY 2010 COLA rates, which had been reduced to account for the phase-in of locality pay. We did not intend to propose the reduced COLA rates because that would have understated the adjustment. Since the 2009 COLA rates did not reflect the phase-in of locality pay, we finalized the FY 2009 COLA rates for RY 2010 through RY 2014.

In the FY 2013 IPPS/LTCH final rule (77 FR 53700 through 53701), we established a new methodology to update the COLA factors for Alaska and Hawaii, and adopted this methodology for the IPF PPS in the FY 2015 IPF final rule (79 FR 45958 through 45960). We adopted this new COLA methodology for the IPF PPS because IPFs are hospitals with a similar mix of commodities and services. We think it is appropriate to have a consistent policy approach with that of other hospitals in Alaska and Hawaii. Therefore, the IPF COLAs for FY 2015 through FY 2017 were the same as those applied under the IPPS in those years. As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), the COLA updates are determined every 4 years, when the IPPS market basket labor-related share is updated. Because the labor-related share of the IPPS market basket was updated for FY 2018, the COLA factors were updated in FY 2018 IPPS/LTCH rulemaking (82 FR 38529). As such, we also updated the IPF PPS COLA factors for FY 2018 (82 FR 36780 through 36782) to reflect the updated COLA factors finalized in the FY 2018 IPPS/LTCH rulemaking.

For FY 2022, we are finalizing our proposal to update the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and adopted for the IPF PPS in the FY 2015 IPF final rule. Specifically, we are finalizing our proposal to update the 2009 OPM COLA factors by a comparison of the growth in the Consumer Price Indices (CPIs) for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We note that for the prior update to the COLA factors, we used the growth in the CPI for Anchorage and the CPI for Honolulu. Beginning in 2018, these indexes were renamed to the CPI for Urban Alaska and the CPI for Urban Hawaii due to the BLS updating its sample to reflect the data from the 2010 Decennial Census on the distribution of the urban population (*https://www.bls.gov/regions/west/factsheet/2018cpirevisionwest.pdf,* accessed January 22, 2021). The CPI for Urban Alaska area covers Anchorage and Matanuska-Susitna Borough in the State of Alaska and the CPI for Urban Hawaii covers Honolulu in the State of Hawaii. BLS notes that the indexes are considered continuous over time, regardless of name or composition changes.

Because BLS publishes CPI data for only Urban Alaska and Urban Hawaii, using the methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule and adopted for the IPF PPS in the FY 2015 IPF final rule, we are finalizing our proposal to use the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these urban areas and the U.S. (as measured by the CPIs) are appropriate proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the U.S.

BLS publishes the CPI for All Items for Urban Alaska, Urban Hawaii, and for the average U.S. city. However, consistent with our methodology finalized in the FY 2013 IPPS/LTCH PPS final rule and adopted for the IPF PPS in the FY 2015 IPF final rule, we are finalizing our proposal to create reweighted CPIs for each of the respective areas to reflect the underlying

composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share is comprised of a different mix of commodities and services. Therefore, we are finalizing our proposal to create reweighted indexes for Urban Alaska, Urban Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and proposed shares of 57 percent commodities/43 percent. We created reweighted indexes using BLS data for 2009 through 2020—the most recent data available at the time of this final rulemaking. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38530), we created reweighted indexes based on the 2014-based IPPS market basket (which was adopted for the FY 2018 IPPS update) and BLS data for 2009 through 2016 (the most recent BLS data at the time of the FY 2018 IPPS/LTCH PPS rulemaking), and we updated the IPF PPS COLA factors accordingly for FY 2018.

We continue to believe this methodology is appropriate because we continue to make a COLA for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent. As stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38530), under the COLA update methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating this cap. In applying this finalized methodology for updating the COLA factors, for FY 2022, we are finalizing our proposal to continue to use such a cap, as our policy is based on OPM's COLA factors (updated by the methodology described above).

Applying this methodology, the COLA factors that we are finalizing our proposal to establish for FY 2022 to adjust the nonlabor-related portion of the standardized amount for IPFs located in Alaska and Hawaii are shown in Table 2. For comparison purposes, we also are showing the COLA factors effective for FY 2018 through FY 2021.

TABLE 2: Comparison of IPF PPS Cost-of-Living Adjustment Factors: IPFs Located in Alaska and Hawaii

Area	FY 2018 through FY 2021	FY 2022 through FY 2025
Alaska:		
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.25	1.22
Rest of Alaska	1.25	1.24
Hawaii:		
City and County of Honolulu	1.25	1.25
County of Hawaii	1.21	1.22
County of Kauai	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25

The final IPF PPS COLA factors for FY 2022 are also shown in Addendum A to this final rule, and is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html.*

4. Final Adjustment for IPFs with a Qualifying Emergency Department (ED)

The IPF PPS includes a facility-level adjustment for IPFs with qualifying EDs. We provide an adjustment to the Federal per diem base rate to account for the costs associated with maintaining a full-service ED. The adjustment is intended to account for ED costs incurred by a psychiatric hospital with a qualifying ED or an excluded psychiatric unit of an IPPS hospital or a CAH, for preadmission services otherwise payable under the Medicare Hospital Outpatient Prospective Payment System (OPPS), furnished to a beneficiary on the date of the beneficiary's admission to the hospital and during the day immediately preceding the date of admission to the IPF (see § 413.40(c)(2)), and the overhead cost of maintaining the ED. This payment is a facility-level adjustment that applies to all IPF admissions (with one exception which we described), regardless of whether a particular patient receives preadmission services in the hospital's ED.

The ED adjustment is incorporated into the variable per diem adjustment for the first day of each stay for IPFs with a qualifying ED. Those IPFs with a qualifying ED receive an adjustment factor of 1.31 as the variable per diem adjustment for day 1 of each patient stay. If an IPF does not have a qualifying ED, it receives an adjustment factor of 1.19 as the variable per diem adjustment for day 1 of each patient stay.

The ED adjustment is made on every qualifying claim except as described in this section of the proposed rule. As specified in § 412.424(d)(1)(v)(B), the ED adjustment is not made when a patient is discharged from an IPPS hospital or CAH and admitted to the same IPPS hospital's or CAH's excluded psychiatric unit. We clarified in the November 2004 IPF PPS final rule (69 FR 66960) that an ED adjustment is not made in this case because the costs associated with ED services are reflected in the DRG payment to the IPPS hospital or through the reasonable cost payment made to the CAH.

Therefore, when patients are discharged from an IPPS hospital or CAH and admitted to the same hospital's or CAH's excluded

psychiatric unit, the IPF receives the 1.19 adjustment factor as the variable per diem adjustment for the first day of the patient's stay in the IPF. For FY 2022, we are finalizing our proposal to continue to retain the 1.31 adjustment factor for IPFs with qualifying EDs. A complete discussion of the steps involved in the calculation of the ED adjustment factors are in the November 2004 IPF PPS final rule (69 FR 66959 through 66960) and the RY 2007 IPF PPS final rule (71 FR 27070 through 27072).

F. Other Final Payment Adjustments and Policies

1. Outlier Payment Overview

The IPF PPS includes an outlier adjustment to promote access to IPF care for those patients who require expensive care and to limit the financial risk of IPFs treating unusually costly patients. In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(3)(i) to provide a per-case payment for IPF stays that are extraordinarily costly. Providing additional payments to IPFs for extremely costly cases strongly improves the accuracy of the IPF PPS in determining resource costs at the patient and facility level. These additional payments reduce the financial losses that would otherwise be incurred in treating patients who require costlier care, and therefore, reduce the incentives for IPFs to under-serve these patients. We make outlier payments for discharges in which an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the Federal per diem payment amount for the case.

In instances when the case qualifies for an outlier payment, we pay 80 percent of the difference between the estimated cost for the case and the adjusted threshold amount for days 1 through 9 of the stay (consistent with the median LOS for IPFs in FY 2002), and 60 percent of the difference for day 10 and thereafter. The adjusted threshold amount is equal to the outlier threshold amount adjusted for wage area, teaching status, rural area, and the COLA adjustment (if applicable), plus the amount of the Medicare IPF payment for the case. We established the 80 percent and 60 percent loss sharing ratios because we were concerned that a single ratio established at 80 percent (like other Medicare PPSs) might provide an incentive under the IPF per diem payment system to increase LOS in order to receive additional payments.

After establishing the loss sharing ratios, we determined the current fixed dollar loss threshold amount through payment simulations designed to compute a dollar loss beyond which payments are estimated to meet the 2 percent outlier spending target. Each year when we update the IPF PPS, we simulate payments using the latest available data to compute the fixed dollar loss threshold so that outlier payments represent 2 percent of total estimated IPF PPS payments.

2. Final Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we are finalizing our proposal to update the fixed dollar loss threshold amount used under the IPF PPS outlier policy. Based on the regression analysis and payment simulations used to develop the IPF PPS, we established a 2 percent outlier policy, which strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the Federal per diem base rate for all other cases that are not outlier cases.

Our longstanding methodology for updating the outlier fixed dollar loss threshold involves using the best available data, which is typically the most recent available data. For this final rulemaking, the most recent available data are the FY 2020 claims. However, during FY 2020, the U.S. healthcare system undertook an unprecedented response to the PHE declared by the Health and Human Services Secretary on January 31, 2020 in response to the outbreak of respiratory disease caused by a novel (new) coronavirus that has been named ''SARS CoV 2'' and the disease it causes, which has been named ''coronavirus disease 2019'' (abbreviated ''COVID–19''). Therefore, as discussed in section VI.C.3 of the FY 2022 IPF PPS proposed rule (86 FR 19524 through 195266), we considered whether the most recent available year of claims, FY 2020, or the prior year, FY 2019, would be the best for estimating IPF PPS payments in FY 2021 and FY 2022. We compared the two years' claims distributions as well as the impact results, and based on that analysis determined that the FY 2019 claims appeared to be the best available data at this time. We refer the reader to section VI.C.3 of the FY 2022 IPF PPS proposed rule (86 FR 19524 through 195266 FR) for a detailed discussion of that analysis.

Comment: We received 2 comments on our analysis of the FY 2019 and FY 2020 claims in determining the best available data for estimating IPF PPS payments in FY 2021 and FY 2022. Both comments were supportive of our proposal to use the FY 2019 claims for this purpose. One of these commenters expressed appreciation for the proposed reduction in the outlier fixed dollar loss threshold. Another commenter agreed with our assessment that FY 2020 claims were heavily impacted by the intensity of the COVID–19 pandemic.

Response: We appreciate these commenters' support. Based on the revised impact analysis discussed in section VI.C.3 of this final rule, we continue to believe that the FY 2019 claims are the best available data for estimating FY 2021 and FY 2022 payments.

Final Decision: We are finalizing as proposed to use the June 2020 update of the FY 2019 IPF claims for updating the outlier fixed dollar loss threshold.

Based on an analysis of the June 2020 update of FY 2019 IPF claims and the FY 2021 rate increases, we believe it is necessary to update the fixed dollar loss threshold amount to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments. We are finalizing our proposal to update the IPF outlier threshold amount for FY 2022 using FY 2019 claims data and the same methodology that we used to set the initial outlier threshold amount in the RY 2007 IPF PPS final rule (71 FR 27072 and 27073), which is also the same methodology that we used to update the outlier threshold amounts for years 2008 through 2021. Based on an analysis of these updated data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 1.9 percent in FY 2021. Therefore, we are finalizing our proposal to update the outlier threshold amount to $14,470 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2022. This final update is a decrease from the FY 2021 threshold of $14,630. In contrast, using the FY 2020 claims to estimate payments, the final outlier fixed dollar loss threshold for FY 2022 would be $22,720, which would have been an increase from the FY 2021 threshold of $14,630. We refer the reader to section VI.C.3 of this final rule for a detailed discussion of the estimated impacts of the final update to the outlier fixed dollar loss threshold.

We note that our use of the FY 2019 claims to set the final outlier fixed dollar loss threshold for FY 2022 deviates from what has been our longstanding practice of using the most recent available year of claims, which is FY 2020 data. However, we are finalizing this policy in a way that remains otherwise consistent with the

established outlier update methodology. As discussed in this section and in section VI.C.3 of this final rule, we are finalizing our proposal to update the outlier fixed dollar loss threshold based on FY 2019 IPF claims in order to maintain the appropriate outlier percentage in FY 2022. We are finalizing our proposal to deviate from our longstanding practice of using the most recent available year of claims only because, and to the extent that, the COVID–19 PHE appears to have significantly impacted the FY 2020 IPF claims. As discussed in section VI.C.3 of this final rule, we have analyzed more recent available IPF claims data and continue to believe that using FY 2019 IPF claims is appropriate for the FY 2022 update. We intend to continue to analyze further data in order to better understand both the short-term and long-term effects of the COVID–19 PHE on IPFs.

3. Final Update to IPF Cost-to-Charge Ratio Ceilings

Under the IPF PPS, an outlier payment is made if an IPF's cost for a stay exceeds a fixed dollar loss threshold amount plus the IPF PPS amount. In order to establish an IPF's cost for a particular case, we multiply the IPF's reported charges on the discharge bill by its overall cost-to-charge ratio (CCR). This approach to determining an IPF's cost is consistent with the approach used under the IPPS and other PPSs. In the FY 2004 IPPS final rule (68 FR 34494), we implemented changes to the IPPS policy used to determine CCRs for IPPS hospitals, because we became aware that payment vulnerabilities resulted in inappropriate outlier payments. Under the IPPS, we established a statistical measure of accuracy for CCRs to ensure that aberrant CCR data did not result in inappropriate outlier payments.

As we indicated in the November 2004 IPF PPS final rule (69 FR 66961), we believe that the IPF outlier policy is susceptible to the same payment vulnerabilities as the IPPS; therefore, we adopted a method to ensure the statistical accuracy of CCRs under the IPF PPS. Specifically, we adopted the following procedure in the November 2004 IPF PPS final rule:

- Calculated two national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas.
- Computed the ceilings by first calculating the national average and the standard deviation of the CCR for both urban and rural IPFs using the most recent CCRs entered in the most recent Provider Specific File (PSF) available.

For FY 2022, we are finalizing our proposal to continue to follow this methodology.

To determine the rural and urban ceilings, we multiplied each of the standard deviations by 3 and added the result to the appropriate national CCR average (either rural or urban). The upper threshold CCR for IPFs in FY 2022 is 2.0261 for rural IPFs, and 1.6879 for urban IPFs, based on CBSA-based geographic designations. If an IPF's CCR is above the applicable ceiling, the ratio is considered statistically inaccurate, and we assign the appropriate national (either rural or urban) median CCR to the IPF.

We apply the national median CCRs to the following situations:

- New IPFs that have not yet submitted their first Medicare cost report. We continue to use these national median CCRs until the facility's actual CCR can be computed using the first tentatively or final settled cost report.
- IPFs whose overall CCR is in excess of three standard deviations above the corresponding national geometric mean (that is, above the ceiling).
- Other IPFs for which the MAC obtains inaccurate or incomplete data with which to calculate a CCR.

We are finalizing our proposal to continue to update the FY 2022 national median and ceiling CCRs for urban and rural IPFs based on the CCRs entered in the latest available IPF PPS PSF. Specifically, for FY 2022, to be used in each of the three situations listed previously, using the most recent CCRs entered in the CY 2021 PSF, we provide an estimated national median CCR of 0.5720 for rural IPFs and a national median CCR of 0.4200 for urban IPFs. These calculations are based on the IPF's location (either urban or rural) using the CBSA-based geographic designations. A complete discussion regarding the national median CCRs appears in the November 2004 IPF PPS final rule (69 FR 66961 through 66964).

IV. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

A. Background and Statutory Authority

We refer readers to the FY 2019 IPF PPS final rule (83 FR 38589) for a discussion of the background and statutory authority [1] of the IPFQR Program.

B. Covered Entities

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we established that the IPFQR Program's quality reporting requirements cover those psychiatric hospitals and psychiatric units paid under Medicare's IPF PPS (§ 412.404(b)). Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals that treat Medicare patients are paid under the IPF PPS. Consistent with previous regulations, we continue to use the terms ''facility'' or IPF to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology in our IPF PPS regulations at § 412.402. For more information on covered entities, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645).

C. Previously Finalized Measures and Administrative Procedures

The current IPFQR Program includes 14 measures. For more information on these measures, we refer readers to Table 5 of this final rule and the following final rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50889 through 50897);
- The FY 2015 IPF PPS final rule (79 FR 45963 through 45975);
- The FY 2016 IPF PPS final rule (80 FR 46695 through 46714);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57238 through 57247);
- The FY 2019 IPF PPS final rule (83 FR 38590 through 38606); and
- The FY 2020 IPF PPS final rule (84 FR 38459 through 38467).

For more information on previously adopted procedural requirements, we refer readers to the following rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53660);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50903);
- The FY 2015 IPF PPS final rule (79 FR 45975 through 45978);
- The FY 2016 IPF PPS final rule (80 FR 46715 through 46719);

[1] We note that the statute uses the term ''rate year'' (RY). However, beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD codes, effective on October 1 of each year. This change allowed for annual payment updates and the ICD coding update to occur on the same schedule and appear in the same **Federal Register** document, promoting administrative efficiency. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the IPF PPS RY means the 12-month period from October 1 through September 30, which we refer to as a ''fiscal year'' (FY) (76 FR 26435). Therefore, with respect to the IPFQR Program, the terms ''rate year,'' as used in the statute, and ''fiscal year'' as used in the regulation, both refer to the period from October 1 through September 30. For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435).

- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57248 through 57249);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38471 through 38474);
- The FY 2019 IPF PPS final rule (83 FR 38606 through 38608); and
- The FY 2020 IPF PPS final rule (84 FR 38467 through 38468).

D. Closing the Health Equity Gap in CMS Quality Programs—Request for Information (RFI)

Persistent inequities in health care outcomes exist in the U.S., including among Medicare patients. In recognition of persistent health disparities and the importance of closing the health equity gap, we requested information on revising several CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for facilities, providers, and patients. The RFI that was included in the proposed rule is part of an ongoing effort across CMS to evaluate appropriate initiatives to reduce health disparities. Feedback will be used to inform the creation of a future, comprehensive, RFI focused on closing the health equity gap in CMS programs and policies.

The RFI contained four parts:

- *Background:* This section provided information describing our commitment to health equity, and existing initiatives with an emphasis on reducing health disparities.
- *Current CMS Disparity Methods:* This section described the methods, measures, and indicators of social risk currently used with the CMS Disparity Methods.
- *Future potential stratification of quality measure results:* This section described four potential future expansions of the CMS Disparity Methods, including (1) Stratification of Quality Measure Results—Dual Eligibility; (2) Stratification of Quality Measure Results—Race and Ethnicity; (3) Improving Demographic Data Collection; and (4) Potential Creation of a Facility Equity Score to Synthesize Results Across Multiple Social Risk Factors.
- *Solicitation of public comment:* This section specified 12 requests for feedback on these topics. We reviewed feedback on these topics and note our intention for an additional RFI or rulemaking on this topic in the future.

1. Background

Significant and persistent inequities in health care outcomes exist in the U.S. Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level, is often associated with worse health outcomes.[2 3 4 5 6 7 8 9] Such disparities in health outcomes are the result of number of factors, but importantly for CMS programs, although not the sole determinant, poor access and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and operative complications.[10 11 12 13 14 15] Readmission rates for common conditions in the Hospital Readmissions Reduction Program are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[16 17 18 19 20] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease, and stroke.[21] The COVID–19 pandemic has further illustrated many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to White persons.[22 23] As noted by the Centers for Disease Control ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.'' [24] One important strategy for addressing these important inequities is improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[25] For the purposes of this final rule, we are using a definition of equity established in

[2] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[3] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[4] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[5] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[6] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[7] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[8] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[9] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[10] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[11] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[12] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: an 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[13] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[14] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[15] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[16] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[17] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[18] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[19] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[20] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[21] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[22] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[23] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[24] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[25] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

Executive Order 13985, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [26] We note that this definition was recently established by the current administration, and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Networks and Quality Improvement Organizations (QIN–QIOs) in their efforts to engage with and assist providers that care for vulnerable populations; Federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[27] The CMS Equity Plan for Improving Quality in Medicare focuses on three core priority areas which inform our policies and programs: (1) Increasing understanding and awareness of health disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity.[28] The CMS Quality Strategy [29] and Meaningful Measures Framework [30] include elimination of racial and ethnic disparities as a central principle. Our efforts aimed at closing the health equity gap to date have included providing transparency about health disparities, supporting providers with evidence-informed solutions to achieve health equity, and reporting to providers on gaps in quality through the following reports and programs:

- The *CMS Mapping Medicare Disparities Tool,* which is an interactive map that identifies areas of disparities and a starting point to understand and investigate geographical, racial and ethnic differences in health outcomes for Medicare patients.[31]
- The *Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage Stratified Report,* which highlights racial and ethnic differences in health care experiences and clinical care, compares quality of care for women and men, and looks at racial and ethnic differences in quality of care among women and men separately for Medicare Advantage plans.[32]
- *The Rural-Urban Disparities in Health Care in Medicare Report,* which details rural-urban differences in health care experiences and clinical care.[33]
- The *Standardized Patient Assessment Data Elements* for certain post-acute care Quality Reporting Programs, which now includes data reporting for race and ethnicity and preferred language, in addition to screening questions for social needs (84 FR 42536 through 42588).
- The *CMS Innovation Center's Accountable Health Communities Model,* which include standardized data collection of health-related social needs data.
- The *Guide to Reducing Disparities* which provides an overview of key issues related to disparities in readmissions and reviews sets of activities that can help hospital leaders reduce readmissions in diverse populations.[34]
- The *CMS Disparity Methods,* which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmission Reduction Program (84 FR 42496 through 42500).

These programs are informed by reports by the National Academies of Science, Engineering and Medicine (NASEM) [35] and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [36] which have examined the influence of social risk factors on several of our quality programs. In this RFI, we addressed only the seventh initiative listed, the CMS Disparity Methods, which we have implemented for measures in the Hospital Readmissions Reduction Program and are considering in other programs, including the IPFQR Program. We discussed the implementation of these methods to date and present considerations for continuing to improve and expand these methods to provide providers and ultimately consumers with actionable information on disparities in health care quality to support efforts at closing the equity gap.

2. Current CMS Disparity Methods

We first sought public comment on potential confidential and public reporting of IPFQR program measure data stratified by social risk factors in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 20121). We initially focused on stratification by dual eligibility, which is consistent with recommendations from ASPE's First Report to Congress which was required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185).[37] This report found that in the context of value-based purchasing (VBP) programs, dual eligibility was among the most powerful predictors of poor health outcomes

[26] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government.*

[27] Centers for Medicare and Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[28] Centers for Medicare and Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[29] Centers for Medicare Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[30] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[31] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[32] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[33] Centers for Medicare and Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. 2019. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf.*

[34] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[35] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[36] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[37] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

among those social risk factors that ASPE examined and tested.

In the FY 2018 IPPS/LTCH PPS final rule we also solicited feedback on two potential methods for illuminating differences in outcomes rates among patient groups within a provider's patient population that would also allow for a comparison of those differences, or disparities, across providers for the Hospital IQR Program (82 FR 38403 through 38409). The first method (the Within-Hospital disparity method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also allows for a comparison of the magnitude of disparity across hospitals, permitting hospitals to assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital method) is complementary and assesses hospitals' outcome rates for dual-eligible patients only, across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. In the FY 2018 IPPS/LTCH PPS proposed rule under the IPFQR Program (82 FR 20121), we also specifically solicited feedback on which social risk factors provide the most valuable information to stakeholders. Overall, comments supported the use of dual eligibility as a proxy for social risk, although commenters also suggested investigation of additional social risk factors, and we continue to consider which risk factors provide the most valuable information to stakeholders.

Concurrent with our comment solicitation on stratification in the IPFQR Program, we have considered methods for stratifying measure results for other quality reporting programs. For example, in the FY 2019 IPPS/LTCH PPS final rule (82 FR 41597 through 41601), we finalized plans to provide confidential hospital-specific reports (HSRs) containing stratified results of the Pneumonia Readmission (NQF #0506) and Pneumonia Mortality (NQF #0468) measures including both the Across-Hospital Disparity Method and the Within-Hospital Disparity Method (disparity methods), stratified by dual eligibility. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41554 through 41556), we also removed six condition/procedure specific readmissions measures, including the Pneumonia Readmission measure (NQF #0506) and five mortality measures, including the Pneumonia Mortality measure (NQF #0468) (83 FR 41556 through 41558) from the Hospital IQR Program. However, the Pneumonia Readmission (NQF #0506) and the other condition/procedure readmissions measures remained in the Hospital Readmissions Reduction Program. In 2019, we provided hospitals with results of the Pneumonia Readmission measure (NQF#0506) stratified using dual eligibility. We provided this information in annual confidential HSRs for claims-based measures.

We then, in the FY 2020 IPPS/LTCH PPS Final Rule (84 FR 42388 through 42390), finalized the proposal to provide confidential hospital specific reports (HSRs) containing data stratified by dual-eligible status for all six readmission measures included in the Hospital Readmission Reduction Program.

3. Potential Expansion of the CMS Disparity Methods

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.[38] As we previously noted, we have been considering, among other things, expanding our efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. We sought public comment on the potential stratification of quality measures in the IPFQR Program across two social risk factors: Dual eligibility and race/ethnicity.

a. Stratification of Quality Measure Results—Dual Eligibility

As described previously in this section, landmark reports by the National Academies of Science, Engineering and Medicine (NASEM) [39] and the Office of the Assistant Secretary for Planning and Evaluation (ASPE),[40] which have examined the influence of social risk factors on several of our quality programs, have shown that in the context of value-based purchasing (VBP) programs, dual eligibility, as an indicator of social risk, is a powerful predictor of poor health outcomes. We noted that the patient population of IPFs has a higher percentage of dually eligible patients than the general Medicare population. Specifically, over half (56 percent) of Medicare patients in IPFs are dually eligible [41] while approximately 20 percent of all Medicare patients are dually eligible.[42] We are considering stratification of quality measure results in the IPFQR Program and are considering which measures would be most appropriate for stratification and if dual eligibility would be a meaningful social risk factor for stratification.

For the IPFQR Program, we would consider disparity reporting using two disparity methods derived from the Within-Hospital and Across-Hospital methods, described in section IV.D.2 of this final rule. The first method (based on the Within-Facility disparity method) would aim to promote quality improvement by calculating differences in outcome rates between dual and non-dual eligible patient groups within a facility while accounting for their clinical risk factors. This method would allow for a comparison of those differences, or disparities, across facilities, so facilities could assess how well they are closing disparity gaps compared to other facilities. The second approach (based on the Across-Facility method) would be complementary and assesses facilities' outcome rates for subgroups of patients, such as dual eligible patients, across facilities, allowing for a comparison among facilities on their performance caring for their patients with social risk factors.

b. Stratification of Quality Measure Results—Race and Ethnicity

The Administration's *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* directs agencies to assess potential barriers that underserved communities and individuals may face to enrollment in and access to benefits and services in Federal Programs. As summarized in section IV.D of this final rule, studies have shown that among Medicare beneficiaries, racial and ethnic minority persons often experience worse health outcomes, including more frequent hospital readmissions and operative

[38] Centers for Medicare Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[39] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[40] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[41] *https://aspe.hhs.gov/basic-report/transitions-care-and-service-use-among-medicare-beneficiaries-inpatient-psychiatric-facilities-issue-brief.*

[42] *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DataStatisticalResources/Downloads/MedicareMedicaidDualEnrollmentEverEnrolledTrendsDataBrief2006-2018.pdf.*

complications. An important part of identifying and addressing inequities in health care is improving data collection to allow us to better measure and report on equity across our programs and policies. We are considering stratification of quality measure results in the IPFQR Program by race and ethnicity and are considering which measures would be most appropriate for stratification.

As outlined in the 1997 Office of Management and Budget (OMB) Revisions to the Standards for the Collection of Federal Data on Race and Ethnicity, the racial and ethnic categories, which may be used for reporting the disparity methods are considered to be social and cultural, not biological or genetic.[43] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. In the OMB standards, Hispanic or Latino is the only ethnicity category included, and since race and ethnicity are two separate and distinct concepts, persons who report themselves as Hispanic or Latino can be of any race.[44] Another example, the ''Race & Ethnicity—CDC'' code system in Public Health Information Network (PHIN) Vocabulary Access and Distribution System (VADS)[45] permits a much more granular structured recording of a patient's race and ethnicity with its inclusion of over 900 concepts for race and ethnicity. The recording and exchange of patient race and ethnicity at such a granular level can facilitate the accurate identification and analysis of health disparities based on race and ethnicity. Further, the ''Race & Ethnicity—CDC'' code system has a hierarchy that rolls up to the OMB minimum categories for race and ethnicity and, thus, supports aggregation and reporting using the OMB standard. ONC includes both the CDC and OMB standards in its criterion for certified health IT products.[46] For race and ethnicity, a certified health IT product must be able to express both detailed races and ethnicities using *any* of the 900 plus concepts in the ''Race & Ethnicity—CDC'' code system in the PHIN VADS, as well as aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity. This approach can reduce burden on providers recording demographics using certified products.

Self-reported race and ethnicity data remain the gold standard for classifying an individual according to race or ethnicity. However, CMS does not consistently collect self-reported race and ethnicity for the Medicare program, but instead gets the data from the Social Security Administration (SSA) and the data accuracy and comprehensiveness have proven challenging despite capabilities in the marketplace via certified health IT products. Historical inaccuracies in Federal data systems and limited collection classifications have contributed to the limited quality of race and ethnicity information in Medicare's administrative data systems.[47] In recent decades, to address these data quality issues, we have undertaken numerous initiatives, including updating data taxonomies and conducting direct mailings to some beneficiaries to enable more comprehensive race and ethnic identification.[48] [49] Despite those efforts, studies reveal varying data accuracy in identification of racial and ethnic groups in Medicare administrative data, with higher sensitivity for correctly identifying White and Black individuals, and lower sensitivity for correctly identifying individuals of Hispanic ethnicity or of Asian/Pacific Islander and American Indian/Alaskan Native race.[50] Incorrectly classified race or ethnicity may result in overestimation or underestimation in the quality of care received by certain groups of beneficiaries.

We continue to work with Federal and private partners to better collect and leverage data on social risk to improve our understanding of how these factors can be better measured in order to close the health equity gap. Among other things, we have developed an Inventory of Resources for Standardized Demographic and Language Data Collection[51] and supported collection of specialized International Classification of Disease, 10th Revision, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental determinants of health, and sponsored several initiatives to statistically estimate race and ethnicity information when it is absent.[52] The Office of the National Coordinator for Health Information Technology (ONC) included social, psychological, and behavioral standards in the 2015 Edition health information technology (IT) certification criteria (2015 Edition), providing interoperability standards (LOINC (Logical Observation Identifiers Names and Codes) and SNOMED CT (Systematized Nomenclature of Medicine—Clinical Terms)) for financial strain, education, social connection and isolation, and others. Additional stakeholder efforts underway to expand capabilities to capture additional social determinants of health data elements include the Gravity Project to identify and harmonize social risk factor data for interoperable electronic health information exchange for EHR fields, as well as proposals to expand the ICD–10 (International Classification of Diseases, Tenth Revision) Z codes, the alphanumeric codes used worldwide to represent diagnoses.[53]

While development of sustainable and consistent programs to collect data on social determinants of health can be considerable undertakings, we recognize that another method to identify better race and ethnicity data is needed in the short term to address the need for reporting on health equity. In working with our contractors, two algorithms have been developed to *indirectly estimate* the race and ethnicity of Medicare beneficiaries (as described further in the following paragraphs). We feel that using indirect estimation can

[43] Executive Office of the President Office of Management and Budget, Office of Information and Regulatory Affairs. Revisions to the standards for the classification of Federal data on race and ethnicity. Vol 62. Federal Register. 1997:58782–58790

[44] *https://www.census.gov/topics/population/hispanic-origin/about.html.*

[45] *https://phinvads.cdc.gov/vads/ViewValueSet.action?id=67D34BBC-617F-DD11-B38D-00188B398520.*

[46] ONC criteria for certified health IT products: *https://www.healthit.gov/isa/representing-patient-race-and-ethnicity.*

[47] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. *Health Care Financing Review, 29*(3), 27–42.

[48] Filice CE, Joynt KE. Examining Race and Ethnicity Information in Medicare Administrative Data. Med Care. 2017;55(12):e170–e176. doi:10.1097/MLR.0000000000000608.

[49] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[50] Centers for Medicare and Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[51] Centers for Medicare and Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[52] *https://pubmed.ncbi.nlm.nih.gov/18567241/, https://pubmed.ncbi.nlm.nih.gov/30506674/,* Eicheldinger C, Bonito A. More accurate racial and ethnic codes for Medicare administrative data. *Health Care Finance Rev.* 2008;29(3):27–42. Haas A, Elliott MN, Dembosky JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Serv Res.* 2019;54(1):13–23. doi:10.1111/1475–6773.13099.

[53] *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

help to overcome the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirectly estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on facilities as these data are derived using existing administrative and census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available.[54] Indirectly estimated data are most commonly used at the population level (such as the facility or health plan-level), where aggregated results form a more accurate description of the population than existing, imperfect data sets. These methods often estimate race and ethnicity using a combination of other data sources which are predictive of self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.[55]

As described in section IV.D.2, we have previously supported the development of two such methods of indirect estimation of race and ethnicity of Medicare beneficiaries. One indirect estimation approach, developed by our contractor, uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, state of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or Asian/Pacific Islander (API).[56] In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups.[57]

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C & D performance data for Medicare Advantage Plans by race and ethnicity.[58] Validation testing reveals concordances with self-reported race and ethnicity of 0.96 through 0.99 for API, Black, Hispanic, and White beneficiaries for MBISG version 2.1.[59] The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial.[60] Indirect estimation can be a statistically reliable approach for calculating population-level equity results for groups of individuals (such as the facility-level) and is not intended, nor being considered, as an approach for inferring the race and ethnicity of an individual.

However, despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration there remains the small risk of unintentionally introducing bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We feel this amount of bias is considerably less than would be expected if stratified reporting was conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for improving demographic data collection to progress. We expressed interest in learning more about, and solicited comments about, the potential benefits and challenges associated with measuring facility equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

c. Improving Demographic Data Collection

Stratified facility-level reporting using dual eligibility and indirectly estimated race and ethnicity would represent an important advance in our ability to provide equity reports to facilities. However, self-reported race and ethnicity data remain the gold standard for classifying an individual according to race or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.[61] Collection and sharing of a standardized set of social, psychological, and behavioral data by facilities, including race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.[62] This could potentially include expansion to

[54] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[55] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[56] Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

[57] Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research,* 54:13–23.

[58] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[59] MBISG 2.1 validation results performed under contract #GS–10F–0012Y/HHSM–500–2016–00097G). Pending public release of the 2021 Part C and D Performance Data Stratified by Race, Ethnicity, and Gender Report, available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[60] Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research,* 54:13–23 and Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

[61] The Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[62] The Office of the National Coordinator for Health Information Technology. United State Core Data for Interoperability Draft Version 2. 2021. *https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf.*

additional social risk factors, such as disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering all demographic questions, and that individual preferences for non-response are maintained.

We are also interested in learning about and solicited comments on current data collection practices by facilities to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, and disability status). Further, we are interested in potential challenges facing facility collection, at the time of admission, of a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act) [63] and standards for interoperable exchange (such as the U.S. Core Data for Interoperability incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria).[64] Advancing data interoperability through collection of a minimum set of demographic data collection, and incorporation of this demographic information into quality measure specifications, has the potential for improving the robustness of the disparity method results, potentially permitting reporting using more accurate, self-reported information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

d. Potential Creation of a Facility Equity Score To Synthesize Results Across Multiple Social Risk Factors

As we describe in section IV.D.3.a of this final rule, we are considering expanding the disparity methods to IPFs and to include two social risk factors (dual eligibility and race/ethnicity). This approach would improve the comprehensiveness of health equity information provided to facilities. Aggregated results from multiple measures and multiple social risk factors, from the CMS Disparity Methods, in the format of a summary score, can improve the usefulness of the equity results. In working with our contractors, we recently developed an equity summary score for Medicare Advantage contract/plans, the Health Equity Summary Score (HESS), with application to stratified reporting using two social risk factors: Dual eligibility and race and as described in *Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score.*[65]

The HESS calculates standardized and combined performance scores blended across the two social risk factors. The HESS also combines results of the within-plan (similar to the Within-Facility method) and across-plan method (similar to the Across-Facility method) across multiple performance measures.

We are considering building a ''Facility Equity Score,'' not yet developed, which would be modeled off the HESS but adapted to the context of risk-adjusted facility outcome measures and potentially other IPF quality measures. We envision that the Facility Equity Score would synthesize results for a range of measures and using multiple social risk factors, using measures and social risk factors, which would be reported to facilities as part of the CMS Disparity Methods. We believe that creation of the Facility Equity Score has the potential to supplement the overall measure data already reported on the *Care Compare* or successor website, by providing easy to interpret information regarding disparities measured within individual facilities and across facilities nationally. A summary score would decrease burden by minimizing the number of measure results provided and providing an overall indicator of equity.

The Facility Equity Score under consideration would potentially:

- Summarize facility performance across multiple social determinants of health (initially dual eligibility and indirectly estimated race and ethnicity); and
- Summarize facility performance across the two disparity methods (that is, the Within-Facility Disparity Method and the Across-Facility Disparity Method) and potentially for multiple measures.

Prior to any future public reporting, if we determine that a Facility Equity Score can be feasibly and accurately calculated, we would provide results of the Facility Equity Score, in confidential facility specific reports, which facilities and their QIN–QIOs would be able to download. Any potential future proposal to display the Facility Equity Score on the Care Compare or successor website would be made through future RFI or rulemaking.

c. Solicitation of Public Comment

We solicited public comments on the possibility of stratifying IPFQR Program measures by dual eligibility and race and ethnicity. We also solicited public comments on mechanisms of incorporating co-occurring disability status into such stratification as well. We sought public comments on the application of the within-facility or across-facility disparities methods IPFQR Program measures if we were to stratify IPFQR Program measures. We also solicited comment on the possibility of facility collection of standardized demographic information for the purposes of potential future quality reporting and measure stratification. In addition, we solicited public comments on the potential design of a facility equity score for calculating results across multiple social risk factors and measures, including race and disability. Any data pertaining to these areas that are recommended for collection for measure reporting for a CMS program and any potential public disclosure on *Care Compare* or successor website would be addressed through a separate and future notice-and-comment rulemaking. We plan to continue working with ASPE, facilities, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all patients and minimizing unintended consequences. We also noted our intention for additional RFIs or rulemaking on this topic in the future.

Specifically, we solicited public comment on the following:

Future Potential Stratification of Quality Measure Results

- The possible stratification of facility-specific reports for IPFQR program measure data by dual-eligibility status given that over half of the patient population in IPFs are dually eligible, including, which measures would be most appropriate for stratification;
- The potential future application of indirect estimation of race and ethnicity to permit stratification of measure data for reporting facility-level disparity results until more accurate forms of self-identified demographic information are available;
- Appropriate privacy safeguards with respect to data produced from the indirect estimation of race and ethnicity to ensure that such data are properly

[63] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[64] *https://www.healthit.gov/sites/default/files/2020-08/2015EdCures_Update_CCG_USCDI.pdf.*

[65] Agniel D, Martino SC, Burkhart Q, et al. Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score. J Gen Intern Med. Published online November 11, 2019 Nov 11. doi: 10.1007/s11606–019–05473–x.

identified if/when they are shared with providers;

- Ways to address the challenges of defining and collecting accurate and standardized self-identified demographic information, including information on race and ethnicity and disability, for the purposes of reporting, measure stratification and other data collection efforts relating to quality.
- Recommendations for other types of readily available data elements for measuring disadvantage and discrimination for the purposes of reporting, measure stratification and other data collection efforts relating to quality, in addition, or in combination with race and ethnicity.
- Recommendations for types of quality measures or measurement domains to prioritize for stratified reporting by dual eligibility, race and ethnicity, and disability.
- Examples of approaches, methods, research, and considerations or any combination of these for use of data-driven technologies that do not facilitate exacerbation of health inequities, recognizing that biases may occur in methodology or be encoded in datasets.

We received comments on these topics.

Comments: Many commenters expressed support for the collection of data to support stratifying or otherwise measuring disparities in care related to dual-eligibility, race and ethnicity, and disability. Some commenters specifically supported the confidential reporting of stratified results to facilities. Several commenters urged CMS to expand data collection and measure stratification to include factors such as language preference, veteran status, health literacy, gender identity, and sexual orientation to provide a more comprehensive assessment of health equity. One commenter urged CMS to collect data on race and ethnicity specifically for patients suffering from psychiatric disorders, while another noted that for the IPF patient population risk factors, such as substance abuse, may be of more importance. One commenter also provided examples of how their health system has successfully collected and begun to analyze patient-level demographic data. Another commenter referred to an existing effort by the National Committee for Quality Assurance to improve the collection of race and ethnicity data as a possible model for improving data collection. This commenter also supported the use of indirect estimation of race and ethnicity for Medicare beneficiaries, noting some concern about the lack of granularity, especially with respect to Native American and Asian populations. One commenter urged CMS to explore how to best identify social determinants of health using current claims data.

While many commenters expressed support for stratification of claims-based measures, many commenters expressed concern that the existing chart-abstracted measures would face limitations when stratified and thus felt the burden of collecting stratification data for these measures significantly outweighed any potential benefit of doing so. Specifically, commenters noted that stratifying the IPF patient population is more vulnerable to statistical concerns during the stratification process than other patient populations (for example, numbers of patients in one or more strata may be insufficient for reliable sampling and calculations) due to low patient volume in some facilities. One commenter suggested that for this and other reasons CMS should develop disparities reporting specifically for the IPF program rather than adopt an approach developed for a different program. A few commenters also questioned the value of stratification of these measures given the current high levels of performance by many IPFs.

One commenter noted that stratified claims-based measures would exclude all privately insured care and thus be less useful. Several commenters stated that interoperability issues such as a lack of EHRs, particularly for IPFs that are smaller or not part of a large hospital or health system, further add to the burden of stratifying chart-abstracted measures and may contribute to bias in the data.

Several commenters also noted that stratification may be challenging due to differences in the patient population served by IPFs compared to other Medicare programs such as acute and long-term care hospitals, for example, age, proportion and reason for dual-eligibility (income versus disability), and substance abuse disorder prevalence. However, several commenters noted many of these same characteristics, as well as the mental and behavioral health needs of patients cared for by IPFs, are evidence of the need to improve data collection and measurement in IPFs. A commenter also recommended further analysis on the predictive power of social risk factors on mental and behavioral health patient outcomes compared to that of the diagnosis requiring treatment. Several commenters recommended CMS further address issues related to the potential stratification of data such as: Patient privacy and the collection and sharing of social risk factors from patient records or through indirect estimation, differing requirements for collection of race and ethnicity data, transparency regarding indirect estimation methods, and differing Medicaid eligibility requirements by state. One commenter related these concerns to public reporting, suggesting support for confidential reporting until these issues are addressed.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

Improving Demographic Data Collection

- Experiences of users of certified health IT regarding local adoption of practices for collection of social, psychological, and behavioral data elements, the perceived value of using these data for improving decision-making and care delivery, and the potential challenges and benefits of collecting more granular, structured demographic information, such as the ''Race & Ethnicity—CDC'' code system.
- The possible collection of a minimum set of social, psychological, and behavioral data elements by hospitals at the time of admission using structured, interoperable data standards, for the purposes of reporting, measure stratification and other data collection efforts relating to quality.

We received comments on these topics.

Comments: We received mixed feedback regarding demographic data collection. Many commenters supported the need for and use of such data, noting that structured, interoperable electronic health data are the gold standard. They also noted that many barriers exist to adopting electronic health information technology systems necessary for capture of these data, particularly in freestanding psychiatric facilities. A commenter stated that the commenter's organization cannot support demographic data collection due to the workload burden it would place on both the IPF and patients and their families. This commenter also noted that the likelihood of patients and families comfortably answering multiple sensitive demographic questions is low, especially upon admission. Another commenter expressed concerns with the current capabilities of the industry to collect these data, specifying a lack of standardization in screening and data collection and need for staff training.

Multiple commenters expressed concern about the patient and family's perception of the organization if given a data collection questionnaire upon admission, noting that they may think the organization is more focused on data collection rather than care.

Other commenters noted the importance of closing the health equity gap through measurement of demographic characteristics. A commenter suggested that agencies leverage the role of nurses in identifying sociodemographic factors and barriers to health equity. Another commenter supported this method, noting that although this may add another step to data collection processes, it would be valuable in addressing health equity gaps. To reduce possible workload burden on organizations that are new to this process, a commenter recommended a staggered approach to data collection, suggesting CMS require providers and facilities to collect data on age and sex by the end of 2022, race and ethnicity by the end of 2023, etc., with the goal of at least 80 percent data completeness with 80 percent accuracy. In addition, commenters suggested reducing burden by adopting standardized screening tools to collect this information, such as ICD–Z-codes, which in practice would allow patients to be referred to resources and initiatives when appropriate. Several commenters encouraged collection of comprehensive social determinants of health and demographic information in addition to race and ethnicity, such as disability, sexual orientation, and primary language. Several commenters provided feedback on the potential use of an indirect estimation algorithm when race and ethnicity are missing/incorrect, and emphasized the sensitivity of demographic information and recommended that CMS use caution when using estimates from the algorithm, including assessing for potential bias, reporting the results of indirect estimation alongside direct self-report at the organizational level for comparison, and establishing a timeline to transition to entirely directly collected data. Commenters also advised that CMS be transparent with beneficiaries and explain why data are being collected and the plans to use these data. A commenter noted that information technology infrastructure should be established in advance to ensure that this information is being used and exchanged appropriately.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

Potential Creation of a Facility Equity Score To Synthesize Results Across Multiple Social Risk Factors

- The possible creation and confidential reporting of a Facility Equity Score to synthesize results across multiple social risk factors and disparity measures.
- Interventions facilities could institute to improve a low facility equity score and how improved demographic data could assist with these efforts.

We received comments on these topics.

Comments: Commenters generally supported ongoing thoughtful investigation into best practices for measuring health equity.

Many commenters expressed concerns about the potential Facility Equity Score. Commenters argued that the current approach used to generate the composite score may not lead to aggregate results, which would not be actionable for many facilities. Commenters also raised concerns about risk adjustment, limitations in stratification variables, and the appropriateness of the current measure set. A commenter noted that although they support thoughtful efforts to categorize performance, the HESS has been established only as a ''proof of concept'' and will require considerable time and resources to produce a valid and actionable measure. The same commenter also noted that HESS scoring was only feasible for less than one-half of Medicare Advantage (MA) plans and as such, may not be practical for many smaller facilities, or facilities whose enrolled populations differ in social risk factor distribution patterns compared to typical MA plans.

Commenters generally did not support use of the Facility Equity Score in public reporting or payment incentive programs, suggesting that it is imperative to first understand any unintended consequences prior to implementation. More specifically, several commenters gave the example of facilities failing to raise the quality of care for at-risk patients while appearing to achieve greater equity due to lower quality of care for patients that are not at risk. A commenter stated the belief that CMS should begin their initiative to improve health equity by using structural health equity measures. Commenters also raised concerns about use of dual-eligibility as a social risk factor due to variations in state-level eligibility for Medicaid, making national comparisons, or benchmarking of facility scores unreliable. Additionally, commenters who expressed data reliability concerns recommended that CMS focus its resources on improving standardized data collection and reporting procedures for sociodemographic data before moving forward with a Facility Equity Score.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

We also received comments on the general topic of health equity in the IPFQR Program.

Comments: Many commenters expressed overall support of CMS' goals to advance health equity. There were some comments regarding the need to further extend and specify the definition of equity provided in the proposed rule. Commenters also noted that equity initiatives should be based on existing disparities and population health goals, be mindful of the needs of the communities served, and work to bridge hospitals with post-acute and community-based providers. Several commenters encouraged CMS to be mindful about whether collection of additional quality measures and standardized patient assessment elements might increase provider burden. Several commenters noted support for consideration of a measure of organizational commitment to health equity, outlining how infrastructure supports delivery of equitable care. A commenter noted the importance of focusing programming on inequities in vaccine-preventable illness. Another commenter noted that CMS may expand their view of equity beyond quality reporting to payment and coverage policies.

We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of the CMS health equity quality measurement efforts. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity quality measurement efforts.

E. Measure Adoption

We strive to put consumers and caregivers first, ensuring they are empowered to make decisions about their own healthcare along with their

clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with our programs. In combination with other efforts across the Department of Health and Human Services (HHS), we believe the IPFQR Program helps to incentivize facilities to improve healthcare quality and value while giving patients and providers the tools and information needed to make the best decisions for them. Consistent with these goals, our objective in selecting quality measures is to balance the need for information on the full spectrum of care delivery and the need to minimize the burden of data collection and reporting. We have primarily focused on measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. When possible, we also propose to incorporate measures that directly evaluate patient outcomes and experience. We refer readers to section VIII.F.4.a. of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645 through 53646) for a detailed discussion of the considerations taken into account in selecting quality measures.

1. Measure Selection Process

Before being proposed for inclusion in the IPFQR Program, measures are placed on a list of measures under consideration (MUC), which is published annually on behalf of CMS by the National Quality Forum (NQF). Following publication on the MUC list, the Measure Applications Partnership (MAP), a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the IPFQR Program, among other Federal programs, and provides input on those measures to the Secretary. We consider the input and recommendations provided by the MAP in selecting all measures for the IPFQR Program. In our evaluation of the IPFQR Program measure set, we identified two measures that we believe are appropriate for the IPFQR Program.

2. COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) [66] Measure for the FY 2023 Payment Determination and Subsequent Years

a. Background

On January 31, 2020, the Secretary declared a PHE for the U.S. in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[67] COVID–19 is a contagious respiratory illness [68] that can cause serious illness and death. Older individuals and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[69]

As of April 2, 2021, the U.S. had reported over 30 million cases of COVID–19 and over 550,000 COVID–19 deaths.[70] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[71] From December 2, 2020 through January 30, 2021, more than 100,000 Americans were in the hospital with COVID–19 at the same time.[72]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[73] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks, or breathes.[74] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[75] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface (although that is not thought to be a common way that COVID–19 spreads),[76] and that in certain circumstances, infection can occur through airborne transmission.[77]

Subsequent to the publication of the proposed rule, the CDC confirmed that the three main ways that COVID–19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.[78] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[79] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between health care personnel (HCP) and patients, or from patient to patient given the close contact that may occur during the provision of care.[80] The CDC has emphasized that health care settings, including long-term care

[66] This measure was previously titled, ''SARS–CoV–2 Vaccination Coverage among Healthcare Personnel.''

[67] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[68] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[69] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[70] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Accessed on April 3, 2021 at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[71] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895.* Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.*

[72] U.S. Currently Hospitalized | The COVID Tracking Project *https://covidtracking.com/data/charts/us-currently-hospitalized.*

[73] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[74] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[75] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[76] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[77] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[78] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on July 15, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[79] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.*

[80] Centers for Disease Control and Prevention. (2020). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission.*

settings, can be high-risk places for COVID–19 exposure and transmission.[81]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[82] On December 11, 2020, FDA issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[83] Subsequently, FDA issued EUAs for additional COVID–19 vaccines.[84]

FDA determined that it was reasonable to conclude that the known and potential benefits of each vaccine, when used as authorized to prevent COVID–19, outweighed its known and potential risks.[85]

As part of its national strategy to address COVID–19, the Biden Administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[86] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including HCP providing direct care to patients with COVID–19, and individuals at highest risk for developing severe illness from COVID–19.[87] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination given the potential for transmission in health care settings and the need to preserve health care system capacity.[88] Research suggests most states followed this recommendation,[89] and HCP began receiving the vaccine in mid-December of 2020.[90]

There are approximately 18 million healthcare workers in the U.S.[91] As of April 3, 2021 the CDC reported that over 162 million doses of COVID–19 vaccine had been administered, and approximately 60 million people had received a complete vaccination course as described in IV.E.b.i of this final rule.[92] By July 15, 2021 the CDC reported that over 336,000,000 doses had been administered, and approximately 160,000,000 people had received a complete vaccination course.[93] President Biden indicated on March 2, 2021 that the U.S. is on track to have sufficient vaccine supply for every adult by the end of May 2021.[94] Subsequent to the publication of the IPF PPS proposed rule, on June 3, 2021, the White House confirmed that there was sufficient vaccine supply for all Americans.[95]

We believe it is important to require that IPFs report HCP vaccination in their facilities in order to assess whether they are taking steps to protect health care workers and to help sustain the ability of IPFs to continue serving their communities throughout the PHE and beyond. Therefore, we proposed a new measure, COVID–19 Vaccination Coverage Among HCP, beginning with the FY 2023 program year. For that program year, IPFs would be required to report data on the measure for the fourth quarter of 2021 (October 1, 2021 through December 31, 2021). For more information about the reporting period, see section V.E.2.c of this final rule. The measure would assess the proportion of an IPF's health care workforce that has been vaccinated against COVID–19.

Although at the time of the proposed rule, data to show the effectiveness of COVID–19 vaccines to prevent asymptomatic infection or transmission of SARS–CoV–2 were limited, we stated our belief that IPFs should report the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.[96] Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,[97] and we believe HCP COVID–19 vaccination in IPFs could similarly increase uptake among that patient population. We also believe that publishing the HCP vaccination rates would be helpful to many patients, including those who are at high-risk for

[81] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[82] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on April 3, 2021 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[83] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. *Available* at *https://www.fda.gov/media/144412/download. (as reissued on May 10, 2021).*

[84] U.S. Food and Drug Administration. (2020). Moderna COVID–19 Vaccine EUA Letter of Authorization. *Available* at *https://www.fda.gov/media/144636/download (as reissued on July 7, 2021);* U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download (as reissued on June 10, 2021).*

[85] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. *Available* at *https://www.fda.gov/media/144412/download (as reissued on May 10, 2021*) and U.S. Food and Drug Administration. (2020). Moderna COVID–19 Vaccine EUA Letter of Authorization. *Available* at *https://www.fda.gov/media/144636/download (as reissued on July 7, 2021);* U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download (as reissued on June 10, 2021).*

[86] *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/.*

[87] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf;* Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[88] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[89] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.*

[90] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.*

[91] *https://www.cdc.gov/niosh/topics/healthcare/default.html#:~:text=HEALTHCARE%20WORKERS,-Related%20Pages&text=Healthcare%20is%20the%20fastest%2Dgrowing,of%20the%20healthcare%20work%20force.*

[92] CDC. COVID Data Tracker. COVID–19 Vaccinations in the United States. Accessed on 4/4/21 at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

[93] CDC. COVID Data Tracker. COVID–19 Vaccinations in the United States. Accessed on 7/6/2021 at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

[94] The White House. Remarks by President Biden on the Administration's COVID–19 Vaccination Efforts. Accessed March 18, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/02/remarks-by-president-biden-on-the-administrations-covid-19-vaccination-efforts/.*

[95] Press Briefing by White House COVID–19 Response Team and Public Health Officials | The White House.

[96] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm.*

[97] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promote Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measure Area of ''Preventive Care.''

b. Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure (''COVID–19 HCP vaccination measure'') is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in facilities such as IPFs.

(1). Measure Specifications

The denominator is the number of HCP eligible to work in the IPF for at least 1 day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[98]

The numerator is the cumulative number of HCP eligible to work in the IPF for at least 1 day during the reporting period and who received a completed vaccination course against COVID–19 since the vaccine was first available or on a repeated interval if revaccination on a regular basis is needed.[99] Vaccination coverage for the purposes of this measure is defined as the estimated percentage of HCP eligible to work at the IPF for at least 1 day who received a completed vaccination course. A completed vaccination course may require one or more doses depending on the EUA for the specific vaccine used.

The finalized specifications for this measure are available at *https://www.cdc.gov/nhsn/nqf/index.html.*

(2). Review by the Measure Applications Partnership

The COVID–19 HCP vaccination measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020,'' [100] a list of measures under consideration for use in various Medicare programs. When the Measure Applications Partnership (MAP) Hospital Workgroup convened on January 11, 2021, it reviewed the MUC List and the COVID–19 HCP vaccination measure. The MAP recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the IPFQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[101] The MAP also stated that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to facilities would allow facilities to benchmark coverage rates and improve coverage in their IPF, and that reducing rates of COVID–19 in HCP may reduce transmission among patients and reduce instances of staff shortages due to illness.[102]

In its preliminary recommendations, the MAP Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[103] To mitigate its concerns, the MAP believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[104] Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 Vaccination Coverage Among HCP measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measures back to MAP once the specifications are further refined.[105] The MAP specifically stated, ''the incomplete specifications require immediate mitigation and further development should continue.'' [106] The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.[107] In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications were further refined, CMS and the CDC met with MAP Coordinating committee on March 15th. Additional information was provided to address vaccine availability, alignment of the COVID–19 Vaccination Coverage Among HCP measure as closely as possible with the data collection for the Influenza HCP vaccination measure (NQF 0431), and clarification related to how HCP are defined. At this meeting, CMS and the CDC presented preliminary findings from the testing of the numerator of COVID–19 Vaccination Coverage Among HCP, which was in process at that time. These preliminary findings showed numerator data should be feasible and reliable. Testing of the numerator of the number of healthcare personnel vaccinated involves a comparison of the data collected through NHSN and independently reported through the Federal pharmacy partnership program for delivering vaccination to LTC facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination, the number of healthcare workers vaccinated in approximately 1,200 facilities, which had data from both systems, the number of healthcare personnel vaccinated was highly correlated between these 2 systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[108] The MAP further noted that the measure would add value to the program measure set by providing visibility into an important intervention to limit COVID–19 infections in healthcare personnel and the patients for whom they provide care.[109]

We value the recommendations of the MAP and considered these recommendations carefully. Section 1890A(a)(4) of the Act requires the Secretary to take into consideration input from multi-stakeholder groups in selecting certain quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as

[98] Centers for Disease Control and Prevention. Contraindications and precautions. *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications.*

[99] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[100] *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212.*

[101] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[102] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[103] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[104] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[105] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 3, 2021 at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.*

[106] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[107] *Ibid.*

[108] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[109] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

possible to address the urgency of the COVID–19 PHE and its impact on vulnerable populations, including IPFs. We continue to engage with the MAP to mitigate concerns and appreciate the MAP's conditional support for the measure.

(3). NQF Endorsement

Under section 1886(s)(4)(D)(i) of the Act, unless the exception of clause (ii) applies, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. Section 1886(s)(4)(D)(ii) of the Act provides an exception to the requirement for NQF endorsement of measures: In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

This measure is not NQF endorsed and has not been submitted to NQF for endorsement consideration. The CDC, in collaboration with CMS, are planning to submit the measure for consideration in the NQF Fall 2021 measure cycle.

Because this measure is not NQF-endorsed, we considered other available measures. We found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP, therefore, we believe the exception in Section 1186(s)(4)(D)(ii) of the Act applies.

c. Data Collection, Submission and Reporting

Given the time-sensitive nature of this measure considering the PHE, in the FY 2022 IPF PPS proposed rule, we proposed that IPFs would be required to begin reporting data on the proposed COVID–19 Vaccination Coverage Among HCP measure beginning October 1, 2021 for the FY 2023 IPFQR Program year (86 FR 19504). Thereafter, we proposed quarterly [110] reporting periods.

To report this measure, facilities would report COVID–19 vaccination data to the NHSN for at least one week each month, beginning in October 2021 for the October 1, 2021 through December 31, 2021 reporting period affecting FY 2023 payment determination and continuing for each quarter in subsequent years. For more details on data submission, we refer readers to section V.J.2.a of this final rule.

We proposed that IPFs would report the measure through the CDC National Healthcare Safety Network (NHSN) web-based surveillance system.[111] While the IPFQR Program does not currently require use of the NHSN web-based surveillance system, we have previously required use of this system. We refer readers to the FY 2015 IPF PPS final rule in which we adopted the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure for additional information on reporting through the NHSN web-based surveillance system (79 FR 45968 through 45970).

IPFs would report COVID–19 vaccination data in the NHSN Healthcare Personnel Safety (HPS) Component by reporting the number of HCP eligible to have worked at the IPF that week (denominator) and the number of those HCP who have received a completed vaccination course of a COVID–19 vaccination (numerator). For additional information about the data reporting requirements, see IV.J.4. of this final rule.

We invited public comment on our proposal to add a new measure, COVID–19 Vaccination Coverage Among HCP, to the IPFQR Program for the FY 2023 payment determination and subsequent years.

Comment: Some commenters supported the proposed COVID–19 Vaccination Coverage Among Healthcare Personnel measure. One commenter observed that data on vaccination coverage are important for patients and for individuals seeking employment at IPFs. Several commenters noted the importance of vaccines to reduce transmission, and one commenter specifically observed that vaccination is particularly important in settings such as IPFs because non-pharmaceutical interventions are challenging in such institutional settings. Another commenter expressed the belief that the measure is methodologically sound.

Response: We thank these commenters for their support.

Comment: Many commenters expressed concern that using NHSN for reporting is too burdensome and disproportionately affects smaller and freestanding IPFs. Some of these commenters further expressed that requiring reporting through NHSN is inconsistent with the removal of Influenza Vaccine Coverage among HCP measure because the rationale for removing the Influenza Vaccine Coverage among HCP measure was the high reporting burden associated with NHSN reporting.

Response: We believe that there are many significant benefits to collecting and reporting data on COVID–19 vaccination coverage among HCP that outweigh its burden. As discussed in our proposal to adopt this measure, HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care (86 FR 19502). The CDC has emphasized that health care settings can be high-risk places for COVID–19 exposure and transmission.[112] In these settings, COVID–19 can spread between health care personnel (HCP) and patients, or from patient to patient given the close contact that may occur during the provision of care.[113]

Subsequent to the publication of the IPF PPS proposed rule, the CDC updated its Science Brief on COVID–19 Vaccines and Vaccination and observed that the growing body of evidence indicates that people who are fully vaccinated with an mRNA vaccine are less likely to have asymptomatic infection or to transmit SARS–CoV–2 to others. The CDC further noted that the studies are continuing on the benefits of the Johnson & Johnson/Janssen vaccine.[114] Therefore we believe that vaccination coverage among HCP will reduce the risk of contracting COVID–19 for patients in IPFs, and that IPFs reporting this information can help patients identify IPFs where they may have lower risk of COVID–19 exposure. Publishing the HCP vaccination rates will be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose IPFs from which to seek treatment.

While we agree with the commenters that there is some burden associated with reporting this measure (see Section (V)(A)(2)(c) of this final rule), we believe the benefits of data collection and

[110] We note that the proposed rule incorrectly read ''annual reporting periods'' however the section of the proposed rule on data submission (IV.J.2.a) correctly described the data submission process and timelines.

[111] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html.* on February 10, 2021.

[112] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[113] Centers for Disease Control and Prevention. (2020). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission.*

[114] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html.*

reporting on COVID–19 vaccination coverage among HCP are sufficient to outweigh this burden. In addition, commenters are correct in noting that when we removed the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure from the IPFQR Program in the FY 2019 IPF PPS final rule, we observed that reporting measure data through the NHSN is relatively more burdensome for IPFs than for acute care hospitals and that this may be especially true for independent or freestanding IPFs (83 FR 38593 through 38595). However, in our analysis of facilities that did not receive full payment updates for FY 2018 and FY 2019 and the reasons these facilities did not receive full payment updates we observed that 98.24 percent and 99.05 percent of IPFs respectively, including small, independent, and freestanding IPFs, successfully reported data for the Influenza Vaccination Coverage Among Health Care Personnel (NQF #0431) measure prior to its removal from the IPFQR Program. For the reasons outlined above, the COVID–19 pandemic and associated PHE has had a much more significant effect on most aspects of society, including the ability of the healthcare system to operate smoothly, than influenza, making the benefits of the COVID–19 Vaccination Among HCP measure greater than those of the Influenza Vaccination Coverage Among Health Care Personnel (NQF #0431) measure.

Comment: Other commenters expressed concern that facilities face duplicative reporting requirements given that other agencies are requiring reporting through systems other than NHSN, such as the HHS TeleTracking site. A few of these commenters recommended that CMS use the TeleTracking site for data reporting and consumer information as opposed to adopting a quality measure. Other commenters recommended that CMS sunset TeleTracking and use NHSN for reporting COVID–19 vaccination coverage data. One commenter recommended that CMS collaborate with CDC to ensure minimal reporting burden.

Response: We recognize that this measure may lead to duplicative reporting requirements if facilities voluntarily report COVID–19 HCP vaccination information to data reporting systems other than NHSN, and we are collaborating with other HHS agencies, including the CDC, to ensure minimal reporting burden and to eliminate duplicative requirements to the extent feasible.

Comment: Some commenters expressed concern about the measure specifications leading to increased reporting burden. Several of these commenters expressed that the proposed quarterly reporting of three weeks of data (one week per month) is excessively burdensome. Other commenters expressed concern that the measure specifications are not aligned with the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431), specifically noting that the COVID Vaccination Coverage Among HCP measure requires data elements (such as contraindications) that are not required for Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431). One commenter observed that including all staff (not just clinical staff or staff directly employed by the IPF) makes the measure unduly burdensome. Another commenter observed that tracking location is challenging in large organizations with staff that work across locations.

Response: We recognize commenters' concern regarding reporting burden associated with the specifications of this measure. We believe that, given the public health importance of vaccination in addressing the COVID–19 PHE, the benefits of requiring reporting outweigh the burden. We believe that reporting these data on a frequent interval would increase their value by allowing the CDC to better track these important public health data while also being a valuable quality measure that supports consumer choice and IPF improvement initiatives. Because the CDC requests data reported on a monthly basis for one week per month, we believe this is an appropriate reporting frequency for our quality measure to ensure that IPFs do not have duplicative reporting requirements to meet the CDC's need for public health data and CMS' quality measure reporting requirements. We further note that while we have sought to align this measure with the Influenza Vaccination Coverage Among HCP measure (NQF #0431), each measure addresses different public health initiatives and therefore complete alignment may not be possible. For example, because influenza vaccinations are provided during the influenza season (that is, October 1 through March 31) these measures have different reporting periods.

Further, we note that while the Influenza Vaccination Coverage Among HCP measure (NQF #0431) does not have a denominator exclusion for HCP with contraindications to the influenza vaccine, there is a numerator category for these HCP. Specifically, the numerator description is as follows: ''HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: . . . (b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other component(s) of the vaccine, or a history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination . . .'' [115] We believe that this numerator element requires the IPF to track HCP's contraindications to the influenza vaccination. Therefore, we disagree with the commenter's statement that the COVID–19 Vaccination Coverage Among HCP measure is more burdensome than the Influenza Vaccination Coverage Among HCP measure due to requiring IPFs to track HCP's contraindications to the vaccine.

Finally, we note that CDC's guidance for entering data requires submission of HCP count at the IPF level [116] and the measure requires reporting consistent with that guidance. We proposed the reporting schedule of monthly reporting of data from only one week a month to provide COVID–19 vaccination coverage data on a more timely basis than annual influenza vaccination coverage (NQF #0431) while also reducing burden on facilities of weekly reporting which has been the reporting cycle for many COVID–19-related metrics during the pandemic. As described in response to previous commenters, we believe that the public health benefits to having these data available are high, and that they therefore outweigh the burden of reporting for systems with multiple facilities or locations. In summary, we recognize that there may be some elements of the measure specifications that increase burden for some IPFs, however given the impact that the COVID–19 PHE has had on society and the healthcare system, we believe that the benefits outweigh this reporting burden.

Comment: Some commenters expressed concern that having some vaccinations require two doses creates undue reporting burden for IPFs. One commenter recommended modelling this measure on the measure under consideration for patient vaccination coverage within the Merit-Based Incentive Payment System (MIPS) program which would require reporting based on receipt of one dose, as opposed to requiring reporting on receipt of a full course of the vaccine. Some commenters

[115] *http://www.qualityforum.org/Projects/n-r/Population_Health_Prevention/0431_InfluenzaImmunizationHCPersonnelForm_CDC.aspx.*

[116] COVID–19 Vaccination Non-LTC Healthcare Personnel TOI (*cdc.gov*).

expressed concern that because it can take up to 28 days for an individual to be fully vaccinated, requiring reporting for HCP who have worked only one day of the reporting period is burdensome or that this disparately affects facilities without access to the one-dose vaccine.

Response: We believe that it is appropriate to require data on HCP who have received complete COVID–19 vaccination courses, because an IPF has more long-term and regular contact with the HCP who work there than an ambulatory care provider, such as those being evaluated under the MIPS Program, has with their patient population. This gives the IPF more ability to track and encourage HCP to receive their complete vaccination course.

We recognize that since a complete vaccination course could take up to 28 days, some IPFs may initially appear to have lower performance than others (based on having access to two dose vaccinations as opposed to one dose vaccination). However, we believe that with the reporting frequency these providers should show rapid improvement as their staff become fully vaccinated. We note that given the highly infectious nature of the COVID–19 virus, we believe it is important to encourage all personnel within the IPF, regardless of patient contact, role, or employment type, to receive the COVID–19 vaccination to prevent outbreaks within the IPF which may affect resource availability and have a negative impact on patient access to care.

Comment: Some commenters recommended deferring measurement of vaccine coverage among HCP until there is at least one vaccine that has received full FDA approval (as opposed to an EUA). A few commenters expressed concern that the long-term effects of the vaccines are unknown and that some HCP concerned about the risk of serious adverse events; one commenter further expressed concerns regarding the rapid development and EUA timelines. A few commenters expressed concerns regarding HCP being unwilling to receive a vaccine which has not received full FDA approval.

Response: We support widespread vaccination coverage, and note that in issuing the EUAs for these vaccines FDA has established that the known and potential benefits of these vaccines outweigh the known and potential risks.[117] Furthermore, as July 15, 2021, more than 336,000,000 doses have been administered in the United States.[118] Although COVID–19 vaccines are authorized for emergency use prevent COVID–19 and serious health outcomes associated with COVID–19, including hospitalization and death,[119] we understand that some HCP may be concerned about receiving the COVID–19 vaccine prior to the vaccine receiving full FDA approval. We also understand that some HCP may be concerned about long-term effects. We note that the COVID–19 Vaccination Coverage Among HCP measure does not require HCP to receive the vaccination, nor does this measure reward or penalize IPFs for the rate of HCP who have received a COVID–19 vaccine. The COVID–19 Vaccination Coverage Among HCP measure requires IPFs to collect and report COVID–19 vaccination data that would support public health tracking and provide beneficiaries and their caregivers information to support informed decision making. Therefore, we believe that it is appropriate to collect and report these data as soon as possible.

Comment: One commenter observed that there are interventions through which an IPF can promote vaccination coverage, such as by removing barriers to access (through means such as extended vaccine clinic hours). This commenter recommended encouraging these interventions as opposed to promoting vaccination coverage among HCP by adopting the COVID–19 Vaccination Coverage Among HCP measure.

Response: We agree with the commenter that there are interventions through which an IPF can increase vaccination coverage by reducing barriers to access. However, we believe that it is appropriate to propose this measure for the IPFQR Program to encourage such interventions by collecting data on vaccination coverage among HCP. We believe that vaccination is an important health intervention that can protect the health of vulnerable patients and the availability of the healthcare system (that is, limiting the number of HCP absent from work due to illness to ensure that patients have access to care).

Comment: Some commenters expressed the belief that it is inappropriate to use IPF payment policies to drive vaccination coverage among HCP. Some commenters expressed concern that this measure could lead facilities to mandate vaccines for staff, with potential unintended consequences (specifically, staff quitting or legal risk for facilities for staff experiencing adverse events). One commenter expressed the belief that the tie to public reporting and potentially IPF payment is an indirect vaccine mandate.

Several commenters recommended CMS not consider this measure for pay-for-reporting because state laws regarding mandates vary and therefore could lead to inconsistent performance through no fault of facilities. One commenter expressed the belief that this measure was developed for public health tracking and is not appropriate for quality assessment.

Response: We note that this measure does not require vaccination coverage among HCP at IPFs; it requires IPFs to report of COVID–19 vaccination rates. Therefore, we believe it is incorrect to characterize this measure as a ''vaccine mandate.'' Furthermore, we note that the historical national average of providers who had received the influenza vaccination, as reported on the then *Hospital Compare* website was 85 percent, 80 percent, and 82 percent respectively for the FY 2017, FY 2018, and FY 2019 payment determinations prior to removal of the Influenza Vaccination Coverage among Healthcare Personnel measure from the IPFQR Program. We do not believe that this represents performance that would be consistent with a widespread ''vaccine mandate'' and therefore we do not believe that a vaccination coverage among HCP measure, including the COVID–19 Vaccination Coverage among HCP measure, inherently leads to ''vaccine mandates.'' However, we believe that data regarding COVID–19 vaccination coverage among HCP are important to empower patients to make health care decisions that are best for them.

Comment: Some commenters expressed concern that the measure does not fully account for potential reasons that HCP may not receive COVID–19 vaccinations. One commenter recommended expanding the exclusions to the measure's calculation, specifically citing religious objections as an exclusion category. Another commenter observed that there is uncertainty about how effective vaccines are for certain populations, such as those with underlying conditions.

[117] *https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.*

[118] CDC COVID Data Tracker.

[119] *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine.*

Response: We recognize that there are many reasons, including religious objections or concerns regarding an individual provider's specific health status, which may lead individual HCP to decline vaccination. The CDC's NHSN tool allows facilities to report on the number of HCP who were offered a vaccination but declined for reasons including religious or philosophical objections.[120] We agree that there is uncertainty about effectiveness among certain patient populations, including those with underlying conditions. The CDC has found that there is evidence of reduced antibody response to or reduced immunogenicity of COVID–19 mRNA vaccine among some immunosuppressed people.[121] However, we note that COVID–19 vaccines may be administered to most people with underlying medical conditions.[122] Therefore, we believe that individual HCP who may have underlying conditions that could affect vaccine efficacy should make the decision of whether to receive the COVID–19 vaccination in discussion with their individual care provider. We believe that vaccination coverage rates are meaningful data for beneficiaries to use in choosing an IPF which can also be used for public health tracking.

Comment: One commenter expressed the concern that this may have an adverse impact on HCP as it is unclear whether in the future individual HCP will be required to pay for the vaccination themselves.

Response: We understand the commenter's concerns that individual HCP may potentially have to pay for the COVID–19 vaccine in the future. In alignment with our pledge to put patients first in all our programs, we believe that it is important to empower patients to work with their doctors and make health care decisions that are best for them.[123] This includes the belief that HCP should be empowered to work with their own healthcare providers to make the health care decisions that are best for them, based on the totality of their circumstances, including potential costs to receive the vaccine and their increased risks of contracting COVID–19 based on occupational exposure.

Comment: Many commenters expressed concern that this measure should not be adopted until there is clarity around the impact of future boosters. These commenters also noted that booster availability could have an impact on vaccination coverage among HCP. One commenter specifically expressed concern regarding past supply chain disruptions and observed that similar issues may affect booster availability in the future.

Response: The COVID–19 Vaccination Coverage among HCP measure is a measure of a completed vaccination course (as defined in section IV.E.2.b.(1) of the FY 2022 IPF PPS proposed rule (86 FR 19502 through 19503) and does not address booster shots. Currently, the need for COVID–19 booster doses has not been established, and no additional doses are currently recommended for HCP. However, we believe that the numerator is sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' and therefore the measure is sufficiently specified to address boosters. We acknowledge the potential for supply chain disruptions or other factors that affect vaccine availability, but we believe that the urgency of adopting the measure to address the current COVID–19 PHE outweighs these potential concerns.

Comment: Some commenters expressed that collecting the data to report this measure is challenging. These commenters observed that because, unlike influenza vaccinations, HCP have received COVID vaccinations from settings outside their places of employment, employers may still be attaining vaccination records from employees. One commenter observed that the data for HCP is housed in separate systems from those typically used for quality reporting.

Response: We recognize that some IPFs may still be obtaining vaccination records from their employees and other personnel that work within their facilities. However, most healthcare settings, including IPFs, have been reporting COVID–19 data to Federal or state agencies for some time and therefore have established the appropriate workflows or other means to obtain these records from employees or other personnel that work within the IPF. Therefore, we believe that IPFs must have the means to obtain the data, either directly from HCP or from other systems in which these data are housed, and that it is appropriate to require IPFs to report these data.

Comment: Another commenter expressed concern that the shortened performance period for the first year may lead to incomplete data. One commenter recommended allowing voluntary reporting without publicly reporting data for the first performance year to account for potential data gaps.

Response: Given that results would be calculated quarterly for this measure, facilities should show rapid progress as they obtain more complete data on vaccination coverage for their HCP. While we understand the desire for a year of voluntary reporting to account for potential data gaps, we believe that the importance of providing patients and their caregivers with data on COVID–19 Vaccination Coverage among HCP at individual IPFs in a timely manner outweighs this concern and should be accomplished as soon as practical.

Comment: A few commenters expressed concern that due to the delay between data collection (which takes place during a quarter) and public reporting (which follows the reporting of the data collected during the quarter, the deadline for which is 4.5 months after the end of the quarter) the data would not be useful by the time they are publicly reported either because they are too old or because the trajectory of the pandemic has changed. One commenter opposed public reporting until data has been reported for several years.

Response: We believe that it is important to make these data available as soon as possible. We agree with commenters that observe that there is a delay between data collection and public reporting for this measure, and note that such a delay exists for all measures in the IPFQR Program. However, we believe that the data will provide meaningful information to consumers in making healthcare decisions because the data will be able to reflect differences between IPFs in COVID–19 vaccination coverage among HCP even if the data do not reflect the current vaccination rates and we believe it will benefit consumers to have these data available as early as possible. We proposed the shortened reporting period for the first performance period to make the COVID–19 Vaccination among HCP measure data available as quickly as possible.

Comment: One commenter observed that the data would not provide consumers a complete picture of infection control procedures because vaccines are only one tactic to prevent and control infections. Another commenter observed that public reporting may lead to comparisons between facilities. An additional commenter recommended a validation process to ensure that consumers can rely on the data.

[120] *https://www.cdc.gov/nhsn/forms/instr/57.220-toi-508.pdf.*

[121] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.htmla.*

[122] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/underlying-conditions.html.*

[123] Home—Centers for Medicare & Medicaid Services | CMS.

Response: While we recognize that the data may not fully represent all activities to prevent and control infections, we believe that the data would be useful to consumers in choosing IPFs, including making comparisons between facilities. We note that we do not currently have a validation process for any measures in the IPFQR Program and refer readers to section IV.J.3 of this final rule where we discuss considerations for a validation program for the IPFQR Program.

Comment: Some commenters recommended deferring the measure until it has been fully tested and NQF endorsed. One commenter observed that the MAP reviewed the measure concept, not the full measure, and therefore it is premature to include it in the IPFQR Program without further review. Another commenter observed that such rapid measure adoption may set a precedent for future rapid measure adoption.

Response: We believe that given the current COVID–19 PHE, it is important to adopt this measure as quickly as possible to allow tracking and reporting of COVID–19 Vaccination Coverage Among HCP in IPFs. This tracking would provide consumers with important information. We refer readers to FY 2022 IPF PPS proposed rule where we discuss our consideration of NQF endorsed measures on the topic of COVID–19 vaccination coverage among healthcare personnel for additional information (86 FR 19503 through 19504). We note that the MAP had the opportunity to review and provide feedback on the full measure in the March 15th meeting. The CDC, in collaboration with CMS, is planning to submit the measure for consideration in the NQF Fall 2021 measure cycle. Finally, we evaluate all measures on a case-by-case basis and therefore the pace at which we propose to adopt one measure is dependent on the measure and the purpose for adopting it.

Comment: One commenter requested clarification for the reporting frequency.

Response: We recognize that the proposed required frequency for reporting, may have been unclear because we referred to ''annual reporting'' periods two times in the proposed rule. Specifically, we referenced annual reporting periods in the first paragraph of section IV.E.2.c (86 FR 19504) and in our burden estimate for the measure (86 FR 19519). Our description of data submission under IV.J.2.a in which we stated that facilities would be required to report the vaccination data to the NHSN for at least one week each month and that if they reported more than one week, the most recent week's data would be used (86 FR 19513) is correct. In that section, we further noted that the CDC would calculate a single quarterly result for summarizing the data reported monthly. In summary, the measure would require monthly reporting of at least one week's data per month. This would be calculated into quarterly results. We note that IPFs are required to report to NHSN sufficient data (that is, vaccination data for at least one week in each month per quarter) to calculate four quarterly results per year, except for the first performance period which depends on only one quarter of data (the vaccination data for at least one week in each month in Q1 of FY 2022). While IPFs can report data to the NHSN at any time, they must report by 4.5 months following the preceding quarter for the purposes of measure calculation. For the first performance period for this measure (that is Q1 of FY 2022), 4.5 months following the end of the quarter is May 15, 2022.

Comment: One commenter requested clarification on which provider types are considered healthcare personnel.

Response: The provider types that are considered healthcare personnel, along with the specifications for this measure, are available at *https://www.cdc.gov/nhsn/nqf/index.html*. The categories of HCP included in this measure are ancillary services employees; nurse employees; aide, assistant, and technician employees; therapist employees; physician and licensed independent practitioner employees; and other HCP. For more detail about each of these categories we refer readers to the Table of Instructions for Completion of the Weekly Healthcare Personnel COVID–19 Cumulative Vaccination Summary Form for Non-Long-Term Care Facilities available at *https://www.cdc.gov/nhsn/forms/instr/57.220-toi-508.pdf*.

Comment: One commenter observed that the definition of ''location'' for measure calculation is unclear.

Response: CDC's guidance for entering data requires submission of HCP count at the IPF level, not at the location level within the IPF.[124]

After consideration of the public comments, we are finalizing the COVD–19 Vaccination Coverage Among Healthcare Personnel measure as proposed for the FY 2023 payment determination and subsequent years.

[124] COVID–19 Vaccination Non-LTC Healthcare Personnel TOI (*cdc.gov*).

3. Follow-Up After Psychiatric Hospitalization (FAPH) Measure for the FY 2024 Payment Determination and Subsequent Years

a. Background

We proposed one new measure, Follow-Up After Psychiatric Hospitalization (FAPH), for the FY 2024 payment determination and subsequent years. The FAPH measure would use Medicare fee-for-service (FFS) claims to determine the percentage of inpatient discharges from an inpatient psychiatric facility (IPF) stay with a principal diagnosis of select mental illness or substance use disorders (SUDs) for which the patient received a follow-up visit for treatment of mental illness or SUD. Two rates would be calculated for this measure: (1) The percentage of discharges for which the patient received follow-up within 7 days of discharge; and (2) the percentage of discharges for which the patient received follow-up within 30 days of discharge.

The FAPH measure is an expanded and enhanced version of the Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure currently in the IPFQR Program. We proposed to adopt the FAPH measure and replace the FUH measure and refer readers to section IV.F.2.d of the FY 2022 IPF PPS proposed rule for our proposal to remove the FUH measure contingent on adoption of the FAPH measure (86 FR 19510). The FUH (NQF #0576) measure uses Medicare FFS claims to determine the percentage of inpatient discharges from an IPF stay with a principal diagnosis of select mental illness diagnoses for which the patient received a follow-up visit for treatment of mental illness, and it excludes patients with primary substance use diagnoses. During the 2017 comprehensive review of NQF #0576, the NQF Behavioral Health Standing Committee (BHSC) recommended expanding the measure population to include patients hospitalized for drug and alcohol disorders, because these patients also require follow-up care after they are discharged.

In 2018, CMS began development of a measure to expand the IPFQR FUH population to include patients with principal SUD diagnoses to address the NQF BHSC recommendation and the CMS Meaningful Measures priority to promote treatment of SUDs. The FAPH measure would expand the number of discharges in the denominator by about 35 percent over the current FUH measure by adding patients with SUD or dementia as principal diagnoses (including patients with any

combination of SUD, dementia, or behavioral health disorders), populations that also benefit from timely follow-up care.

Furthermore, compared to the criteria for provider type in the current FUH measure, the FAPH measure does not limit the provider type for the follow-up visit if it is billed with a diagnosis of mental illness or SUD. During the measure's testing, the most frequent provider types for the FAPH measure were family or general practice physicians, internal medicine physicians, nurse practitioners, and physician assistants. The technical expert panel (TEP) convened by our contractor agreed that these provider types should be credited by the measure for treating mental illness and SUD and confirmed that this is aligned with integrated care models that aim to treat the whole patient. The TEP further noted that in areas where there are shortages of mental health or SUD clinicians, other types of providers are often the only choice for follow-up treatment. Allowing visits to these types of providers to count towards the numerator allows the measure to capture the rates of appropriate follow-up care more accurately in areas with provider shortages.

Performance on the FAPH measure indicates that follow-up rates for patients hospitalized with mental illness or SUD are less than optimal and that room for improvement is ample. The clinical benefits of timely follow-up care after hospitalization, including reduced risk of readmission and improved adherence to medication, are well-documented in the published literature.[125 126 127 128 129 130 131]

Behavioral health patients in particular have a number of risk factors that underscore the need for timely follow-up and continuity of care: Behavioral health patients have higher baseline hospitalization rates, higher hospital readmission rates, and higher health care costs as compared with the general population of patients.[132 133] Among patients with serious mental illness, 90 percent have comorbid clinical conditions such as hypertension, cardiovascular disease, hyperlipidemia, or diabetes.[134] Among patients hospitalized for general medical conditions, those who also have a mental illness are 28 percent more likely to be readmitted within 30 days than their counterparts without a psychiatric comorbidity.[135] The high prevalence of clinical comorbidities among behavioral health patients, combined with the compounding effect of mental illness on patients with general medical conditions, suggests that behavioral health patients are uniquely vulnerable and supports the intent of the measure to increase follow-up after hospitalization.

In addition, clinical practice guidelines stress the importance of continuity of care between settings for patients with mental illness and SUD. For the treatment of SUD patients, the 2010 guidelines of the American Psychiatric Association (APA) state: ''It is important to intensify the monitoring for substance use during periods when the patient is at a high risk of relapsing, including during the early stages of treatment, times of transition to less intensive levels of care, and the first year after active treatment has ceased.'' [136] This statement is accompanied by a grade of [I], which indicates the highest level of APA endorsement: ''recommended with substantial clinical evidence.''

Evidence supports that outpatient follow-up care and interventions after hospital discharges are associated with a decreased risk of readmissions for patients with mental illness.[137 138] IPFs can influence rates of follow-up care for patients hospitalized for mental illness or SUD. Three studies reported that with certain interventions—such as pre-discharge transition interviews, appointment reminder letters or reminder phone calls, meetings with outpatient clinicians before discharge, and meetings with inpatient staff familiar to patients at the first post-discharge appointment—facilities achieved 30-day follow-up rates of 88 percent or more.[139 140 141] This is substantially higher than the national rate of about 52 percent observed in the current FUH measure for Medicare FFS discharges between July 1, 2016, and June 30, 2017.[142] Medicare FFS data from July 1, 2016, to June 30, 2017, show the national 7-day follow-up rate to be 35.5 percent and the 30-day rate to be 61.0 percent. These data reveal wide variation in follow-up rates across facilities, with a 16.9 percent absolute difference between the 25th and 75th

[125] Tong, L., Arnold, T., Yang, J., Tian, X., Erdmann, C., & Esposito, T. (2018). The association between outpatient follow-up visits and all-cause non-elective 30-day readmissions: A retrospective observational cohort study. *PloS one, 13*(7), e0200691. *https://doi.org/10.1371/journal.pone.0200691*.

[126] Terman, S. W., Reeves, M. J., Skolarus, L. E., & Burke, J. F. (2018). Association Between Early Outpatient Visits and Readmissions After Ischemic Stroke. *Circulation. Cardiovascular quality and outcomes, 11*(4), e004024. *https://doi.org/10.1161/CIRCOUTCOMES.117.004024*.

[127] First Outpatient Follow-Up After Psychiatric Hospitalization: Does One Size Fit All? (2014). *Psychiatric Services,* 66(6), 364–372. *https://doi.org/10.1176/appi.ps.201400081*.

[128] Terman, S. W., Reeves, M. J., Skolarus, L. E., & Burke, J. F. (2018). Association Between Early Outpatient Visits and Readmissions After Ischemic Stroke. *Circulation. Cardiovascular quality and outcomes, 11*(4), e004024. *https://doi.org/10.1161/CIRCOUTCOMES.117.004024*.

[129] Jackson, C., Shahsahebi, M., Wedlake, T., & DuBard, C. A. (2015). Timeliness of outpatient follow-up: An evidence-based approach for planning after hospital discharge. *Annals of family medicine, 13*(2), 115–122. *https://doi.org/10.1370/afm.1753*.

[130] Hernandez, A. F., Greiner, M. A., Fonarow, G. C., Hammill, B. G., Heidenreich, P. A., Yancy, C. W., Peterson, E. D., & Curtis, L. H. (2010). Relationship between early physician follow-up and 30-day readmission among Medicare beneficiaries hospitalized for heart failure. *JAMA, 303*(17), 1716–1722. *https://doi.org/10.1001/jama.2010.533*.

[131] Nadereh Pourat, Xiao Chen, Shang-Hua Wu and Anna C. Davis. Timely Outpatient Follow-up Is Associated with Fewer Hospital Readmissions among Patients with Behavioral Health Conditions. *The Journal of the American Board of Family Medicine*. May 2019, 32 (3) 353–361; DOI: *https://doi.org/10.3122/jabfm.2019.03.180244*.

[132] Germack, H.D., et al. (2019, January). Association of comorbid serious mental illness diagnosis with 30-day medical and surgical readmissions. JAMA Psychiatry.

[133] First Outpatient Follow-Up After Psychiatric Hospitalization: Does One Size Fit All? (2014). *Psychiatric Services,* 66(6), 364–372. *https://doi.org/10.1176/appi.ps.201400081*.

[134] First Outpatient Follow-Up After Psychiatric Hospitalization: Does One Size Fit All? (2014). *Psychiatric Services,* 66(6), 364–372. *https://doi.org/10.1176/appi.ps.201400081*.

[135] Benjenk, I., & Chen, J. (2018). Effective mental health interventions to reduce hospital readmission rates: A systematic review. Journal of hospital management and health policy, 2, 45. *https://doi.org/10.21037/jhmhp.2018.08.05*.

[136] American Psychiatric Association. Practice guideline for the treatment of patients with substance use disorders. 2010. *http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf*.

[137] Kurdyak P, Vigod SN, Newman A, Giannakeas V, Mulsant BH, Stukel T. Impact of Physician Follow-Up Care on Psychiatric Readmission Rates in a Population-Based Sample of Patients With Schizophrenia. Psychiatr Serv. 2018;69(1):61–68. doi: 10.1176/appi.ps.201600507.

[138] Marcus SC, Chuang CC, Ng-Mak DS, Olfson M. Outpatient follow-up care and risk of hospital readmission in schizophrenia and bipolar disorder. Psychiatr Serv. 2017;68(12):1239–1246. doi: 10.1176/appi.ps.201600498.

[139] Batscha C, McDevitt J, Weiden P, Dancy B. The effect of an inpatient transition intervention on attendance at the first appointment post discharge from a psychiatric hospitalization. J Am Psychiatr Nurses Assoc. 2011;17(5):330–338. doi: 10.1177/1078390311417307.

[140] Agarin T, Okorafor E, Kailasam V, et al. Comparing kept appointment rates when calls are made by physicians versus behavior health technicians in inner city hospital: literature review and cost considerations. Community Ment Health J. 2015;51(3):300–304. doi: 10.1007/s10597–014–9812-x.

[141] Olfson M, Mechanic D, Boyer CA, Hansell S. Linking inpatients with schizophrenia to outpatient care. Psychiatr Serv. 1998;49(7):911–917. doi: 10.1176/ps.49.7.911. Quality AFHRA. 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Services USDoHaH; 2018.

[142] *https://data.cms.gov/provider-data/archived-data/hospitals*.

percentiles for the 7-day rate and a 17.4 percent absolute difference for the 30-day rate. If all facilities achieved the benchmark follow-up rates for their Medicare FFS patients (as calculated using the AHRQ Achievable Benchmarks of Care method,)[143] 53,841 additional discharges would have a 7-day follow-up visit, and 47,552 would have a 30-day follow-up visit.[144]

During the development process, we used the CMS Quality Measures Public Comment Page to ask for public comments on the measure.[145] We accepted public comments from January 25, 2019, to February 13, 2019. During this period, we received comments from 29 organizations or individuals. Many commenters acknowledged the importance of developing a measure that assesses acute care providers for follow-up post-hospitalization. Some commenters expressed skepticism about the measure's appropriateness as a tool for evaluating the performance of discharging IPFs due to factors beyond the IPFs' control that can affect whether a patient receives timely post-discharge follow-up care. Ten stakeholders expressed support for the measure based on the expanded list of qualifying diagnoses in the denominator and the inclusion of more patients who could benefit from post-discharge follow-up visits.[146]

We reviewed the comments we received with the TEP, whose members shared similar feedback regarding the importance of follow-up for patients with both mental health diagnoses and substance use disorders, as well as concerns about the ability of IPFs to influence follow-up care. We agree with commenters that some factors that influence follow-up are outside of an IPF's control. However, as described previously in this section, we believe that there are interventions (such as pre-discharge transition interviews, appointment reminder letters or reminder phone calls, meetings with outpatient clinicians before discharge, and meetings with inpatient staff familiar to patients at the first post-discharge appointment) that allow facilities to improve their follow-up adherence. We remain committed to monitoring follow-up to improve health outcomes and view this measure as an expansion of our ability to measure appropriate follow-up care established by FUH.

b. Overview of Measure

(1). Measure Calculation

The FAPH measure would be calculated by dividing the number of discharges that meet the numerator criteria by the number that meet the denominator criteria. Two rates are reported for this measure: the 7-day rate and the 30-day rate.

(a) Numerator

The first rate that would be reported for this measure includes discharges from an IPF that are followed by an outpatient visit for treatment of mental illness or SUD within 7 days. The second rate reported for this measure would include discharges from an IPF that are followed by an outpatient visit for treatment of mental illness or SUD within 30 days. Outpatient visits are defined as outpatient visits, intensive outpatient encounters, or partial hospitalization and are defined by the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), and Uniform Billing (UB) Revenue codes. Claims with codes for emergency room visits do not count toward the numerator.

(b) Denominator

The denominator includes discharges paid under the IPF prospective payment system during the performance period for Medicare FFS patients with a principal diagnosis of mental illness or SUD. Specifically, the measure includes IPF discharges for which the patient was:

- Discharged with a principal diagnosis of mental illness or SUD that would necessitate outpatient follow-up care,
- Alive at the time of discharge,
- Enrolled in Medicare Parts A and B during the month of the discharge date and at least one month after the discharge date to ensure that data are available to capture the index admission and follow-up visits, and
- Age 6 or older on the date of discharge, because follow-up treatment for mental illness or SUD might not always be recommended for younger children.

The denominator excludes IPF discharges for patients who:

- Were admitted or transferred to acute and non-acute inpatient facilities within the 30-day follow-up period, because admission or transfer to other institutions could prevent an outpatient follow-up visit from taking place,
- Were discharged against medical advice, because the IPF could have limited opportunity to complete treatment and prepare for discharge,
- Died during the 30-day follow-up period, or
- Use hospice services or elect to use a hospice benefit at any time during the measurement year regardless of when the services began, because hospice patients could require different follow-up services.

The FAPH measure differs from FUH mostly in the expansion of the measure population to include SUD and other mental health diagnoses in the measure's denominator, but it includes some additional differences:

- The FAPH measure simplifies the exclusion of admission or transfer to acute or non-acute inpatient facilities within 30 days after discharge by aligning with the HEDIS® Inpatient Stay Value Set used in both the HEDIS® FUH and the HEDIS® Follow-Up After Emergency Department Visit for Alcohol and Other Drug Abuse or Dependence (FUA) measures to identify acute and non-acute inpatient stays. A discharge is excluded from the FAPH measure if it is followed by an admission or a transfer with one of the codes in the value set.
- The FAPH measure uses Medicare UB Revenue codes (rather than inpatient discharge status code, which the FUH measure uses) to identify discharge or transfer to other health care institutions. This is to align better with the intent of the HEDIS® FUH and HEDIS® FUA measures.
- The FAPH measure allows mental illness or SUD diagnoses in any position on the follow-up visit claim to count toward the numerator and does not require that it be in the primary position as the FUH measure does.

(2) Measure Reliability and Validity

In 2019, CMS used the final measure specifications to complete reliability and validity testing, which revealed that the FAPH measure provides reliable and valid IPF-level rates of follow-up after psychiatric hospitalization. We evaluated measure reliability based on a signal-to-noise analysis,[147] in which a score of 0.0 implies that all variation is attributed to measurement error (noise), and a score of 1.0 implies that all measure score variation is caused by a real difference in performance across IPFs. Using that approach, we established a minimum denominator size of 40 discharges to attain an overall

[143] *https://nhqrnet.ahrq.gov/inhqrdr/resources/methods#Benchmarks.*

[144] Quality AfHRa. 2017 National Healthcare Quality and Disparities Report. Rockville, MD: Services USDoHaH; 2018.

[145] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/IPF_-Follow-Up-After-Psychiatric-Hospitalization_Public-Comment-Summary.pdf.*

[146] Mathematica. FAPH public comment summary. April 2019.

[147] For additional information on reliability tests see *http://www.qualityforum.org/Measuring_Performance/Improving_NQF_Process/Measure_Testing_Task_Force_Final_Report.aspx.*

reliability score of 0.7 for both the 7-day and the 30-day rate. These analyses revealed that the measure can reliably distinguish differences in performance between IPFs with adequate denominator size.

We evaluated the validity of the measure based on its correlation to two conceptually related measures in the IPFQR Program: The 30-Day All-Cause Unplanned Readmission After Psychiatric Discharge from an IPF (IPF Readmission) measure, and the Medication Continuation Following Inpatient Psychiatric Discharge (Medication Continuation) measure. We observed a weak negative correlation between FAPH and the IPF Readmission measure for both 7-day (—0.11) and 30-day (—0.18) measure rates. This negative correlation is expected because a higher score is indicative of better quality of care for the FAPH, while a lower score is indicative of better quality of care for the IPF readmission measure (that is, a lower rate of unplanned readmissions). High rates of follow-up after visits after discharge and low rates of unplanned readmissions both indicate good care coordination during the discharge process. We observed a weak positive correlation between the 7-day FAPH measure rate and the Medication Continuation measure (0.32), and between the 30-day FAPH measure rate and the Medication Continuation measure (0.42). This result is expected because for both the FAPH and the Medication Continuation measures higher scores are indicative of better-quality care. Follow-up visits after discharge and continuation of medication after discharge both indicate good care coordination during the discharge process. After reviewing these results and the proposed measure specifications, all 13 TEP members who were present agreed that the measure had face validity.[148]

(3) Review by the Measure Applications Partnership and NQF

Under section 1890A(a)(2) of the Act, this measure was included in a publicly available document: ''List of Measures Under Consideration for December 1, 2019,'' available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2018.pdf.*

On January 15, 2020, the MAP Coordinating Committee rated the measure as ''Conditional Support for Rulemaking'' contingent upon NQF endorsement. We submitted the measure to the NQF for endorsement in the spring 2020 cycle. However, some members of the NQF Behavioral Health and Substance Use Standing Committee were concerned about the measure's exclusions for patients who died during the 30-day follow-up period or who were transferred. In addition, some members objected to combining persons with a diagnosis of SUD and those with a diagnosis for a mental health disorder into a single measure of follow-up care. Therefore, the NQF declined to endorse this measure. We noted that the exclusions for patients who died or who were admitted or transferred to an acute or non-acute inpatient facility during the 30-day follow up period align with the FUH measure currently in the IPFQR Program.

Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure for the IPFQR Program that is not endorsed by NQF. The exception to the requirement to specify an endorsed measure states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

The FAPH measure is not NQF endorsed. We have reviewed NQF-endorsed and other consensus-endorsed measures related to follow-up care and identified the FUH measure (NQF #0576) currently in the IPFQR Program and Continuity of Care after Inpatient or | Residential Treatment for SUD (NQF #3453), we believe that the FAPH measure is an improvement over the current FUH measure and over the Continuity of Care after Inpatient or Residential Treatment of Substance Use Disorder because we believe that it is important to ensure appropriate access to follow-up treatment for the largest patient population possible and the FAPH measure applies to a larger patient population than either of the measures we considered. Therefore, we proposed to adopt the FAPH measure described in this section for the FY 2024 payment determination and subsequent years.

c. Data Collection, Submission and Reporting

FAPH uses Medicare FFS Part A and Part B claims that are received by Medicare for payment purposes. The measure links Medicare FFS claims submitted by IPFs and subsequent outpatient providers for Medicare FFS IPF discharges. Therefore, no additional data collection would be required from IPFs. For additional information on data submission for this measure, see section IV.J.2.b of this final rule. The performance period used to identify cases in the denominator is 12 months. Data from this period and 30 days afterward are used to identify follow-up visits in the numerator. Consistent with other claims-based measures in the IPFQR Program, the performance period for this measure is July 1 through June 30. For example, for the FY 2024 payment determination, the performance period would include discharges between July 1, 2021 and June 30, 2022.[149]

We invited public comment on our proposal to add a new measure, Follow-Up After Psychiatric Hospitalization, to the IPFQR Program, beginning with the FY 2024 payment determination and subsequent years.

We received the following comments on our proposal.

Comment: Many commenters supported the adoption of the FAPH measure. Some commenters expressed that the expanded cohort would improve the measure's value. Some commenters expressed that expanding the eligible provider types for the follow-up visit would improve care because of the shortage of psychiatrists. A few commenters observed that care transitions are important, and that outpatient follow-up serves to improve the value of the inpatient services provided. One commenter expressed that adoption of this measure is timely due to the increased behavioral health needs associated with the COVID–19 pandemic. One commenter recommended using this measure at the health system level to better identify care coordination, access, and referral network adequacy.

Response: We thank these commenters for their support. We agree that the expanded definitions would improve the measure's applicability and capture more follow-up visits. Regarding the commenter's

[148] Face validity is defined as a subjective determination by experts that the measure appears to reflect quality of care, done through a systematic and transparent process, that explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality, with degree of consensus and any areas of disagreement provided/discussed: *https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Docs/Evaluation_Guidance.aspx.*

[149] If data availability or operational issues prevent use of this performance period, we would announce the updated performance period through subregulatory communications including announcement on a CMS website and/or on our applicable listservs.

recommendation on using this measure at the health system level, we believe the commenter is recommending adopting this measure to evaluate performance of regional or local health systems (such as those affiliated with large hospital networks). We note that the IPFQR Program applies to Medicare participating freestanding psychiatric hospitals and psychiatric units and we believe that health systems that have IPFs that participate in the IPFQR Program would find this measure useful as they assess access and referral network adequacy within their systems.

Comment: Some commenters observed that some follow-ups, especially for substance use disorders, may not be identifiable in claims. A few commenters specifically noted that some providers who often provide follow-ups are not covered by Medicare (for example, therapists) or that some follow-ups may be covered by other insurers. These commenters observed that this may lead the measure to undercount follow-ups provided. A few of these commenters did not support measure adoption because of this undercount. However, one commenter that expressed this concern supported measure adoption because the commenter believes that burden reduction associated with claims reporting outweighs the potential undercounting.

Response: We acknowledge that, like the Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure that we proposed to replace with the FAPH measure, the FAPH measure would not be able to capture follow-up visits provided by professionals outside of Medicare, or if the patient uses another payer or self-pay to cover the patient's follow-up care, which could lead to an undercount. However, we believe that the data captured by the measure would be sufficient to inform consumers and to provide data for quality improvement initiatives. Further, we agree with the commenter that the burden reduction associated with using claims-based measures outweighs the potential undercounting.

Comment: Some commenters expressed concern that this measure may be difficult for some IPFs to perform well on due to factors outside of the IPF's control. One commenter observed that many rural hospitals lack community resources and therefore cannot refer patients to outpatient psychiatrists. Another commenter observed that some patients may be unwilling to see an outpatient psychiatrist. Other commenters observed that this measure captures patient behavior, not provider actions. Some of these commenters observed that lack of transportation, access barriers, homelessness or other patient characteristics outside of the IPF's control may affect performance. Some of these commenters expressed preference for a process measure that tracks whether IPFs performed interventions to improve follow-up rates before or during discharge.

Response: We recognize that there is regional variation in access to outpatient resources and that patients have varying comfort levels with different provider types. However, we believe that this updated measure helps to address some of the commenters' concerns. Specifically, we note that this measure expands the definition of follow-up to include a wider range of outpatient providers, including family or general practice physicians, internal medicine physicians, nurse practitioners, and physician assistants. We agree with commenters that there are factors that influence follow-up that are outside of an IPF's control (including patient behavior, lack of transportation, access barriers, homelessness, among others).

As described in the FY 2022 IPF PPS proposed rule (86 FR 19504 through 19505), there are interventions that allow facilities to improve their follow-up adherence. We believe it is incumbent upon facilities to identify potential barriers to follow-up adherence and apply appropriate interventions to improve adherence. We believe that this measure is preferable to a process measure because it provides insight into the success of interventions by identifying follow-up rates. As discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50894 through 50895) and the FY 2022 IPF PPS proposed rule in our proposal to adopt the FAPH measure (86 FR 19504 through 19507) we do not expect 100 percent of patients discharged from IPFs to receive follow-up care within 7 or 30 days of discharge because of factors both within and outside of the control of facilities such as availability of providers in the referral network.

Comment: Some commenters opposed the FAPH measure because it is not NQF endorsed and because it was not fully supported by the MAP. A few commenters observed that the measure may undergo changes to achieve NQF endorsement which would create burden if the measure were in the program when these changes occurred. Some commenters recommended delaying implementation until NQF's concerns are fully addressed. One commenter observed that the similar NQF-endorsed FUH measure is available and therefore CMS has not properly considered available consensus endorsed measures.

Response: We appreciate the commenters' concerns about the FAPH measure's lack of NQF endorsement. As we stated in the proposed rule, after having given due consideration to similar measures, FUH measure (NQF #0576) and Continuity of Care after Inpatient or Residential Treatment for SUD (NQF #3453), we believe that the FAPH measure is an improvement over the FUH measure currently in the IPFQR Program (86 FR 19507). The FAPH measure expands the number of discharges in the denominator by adding patients with SUD or dementia, populations that also benefit from timely follow-up care. We propose updates to the IPFQR program measure set on an annual basis through the rulemaking process. During the measure evaluation process, we carefully consider the potential burden to clinicians, health systems, and patients of any updates that are under consideration.

The primary concerns of some NQF Behavioral Health and Substance Use Standing Committee members with the FAPH measure were exclusions for patients who died during the 30-day follow-up period or who were transferred. While we respect the NQF's concerns, we note that these same exclusions align with the exclusions in the Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure which is already NQF endorsed, and which we adopted under the IPFQR Program in the FY 2014 IPPS/LTCH PPS final rule. This measure has a very similar denominator (78 FR 50893 through 50895). The clinical expert work group and technical expert panel convened by our contractor supported these exclusions as being appropriate for both measures.

After having given due consideration to similar measures, FUH measure (NQF #0576) and Continuity of Care after Inpatient or Residential Treatment for SUD (NQF #3453), we believe that the FAPH measure is an improvement over the FUH measure which is currently in the IPFQR Program, because it includes patients with SUD or dementia, populations that also benefit from timely follow-up care (86 FR 19504 through 19506).

Comment: Some commenters recommended further research or testing. Some commenters recommended that CMS continue to consider evidence supporting the expanded patient cohort.

Response: We thank commenters for these recommendations and will

continue to evaluate them as part of our measure monitoring and evaluation process. We believe that the evidence cited in our proposal, including the evidence supporting the APA grade of [I] applied to the 2010 guidelines for the treatment of SUD patients that state ''It is important to intensify the monitoring for substance use during periods when the patient is at a high risk of relapsing, including during the early stages of treatment, times of transition to less intensive levels of care, and the first year after active treatment has ceased'' [150] is sufficient evidence to support measuring follow up after hospitalization for SUD. We note that because discharge from an IPF is a time of transition to less intensive levels of care these guidelines apply to discharge from an IPF and support the expanded patient cohort.

Comment: One commenter requested CMS specifically consider the impact of the physician self-referral law (commonly referred to as ''the Stark Law'') on an IPF's ability to ensure necessary SUD follow-up care. Some commenters recommended that CMS evaluate additional risk adjustment for social risk factors. One commenter further expressed that this measure may not be a successful strategy for reducing readmissions. Another commenter recommended that CMS investigate whether FAPH is an appropriate replacement for the Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB–3/3a) measure.

Response: Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity.[151] We believe that the comment regarding the physician self-referral law relates to compensation arrangements between IPFs (which qualify as hospitals, and ''entities'', for purposes of the physician self-referral law) and physicians who provide post-discharge SUD follow-up care that may implicate the physician self-referral law. To the extent an IPF enters into a compensation arrangement with a physician who provides SUD follow-up care to patients discharged from the hospital, we note that there are exceptions to the physician self-referral law applicable to such compensation arrangements, including recently finalized exceptions for value-based arrangements.

We will consider this measure for potential risk adjustment or stratification as we seek to close the equity gap as described in section IV.D of this final rule. We note that a reduction in readmissions is this measure's objective, though improved follow-up adherence may serve to reduce readmissions because of improved continuity of care. Finally, we will evaluate whether the FAPH measure is an appropriate replacement for Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Disorder Treatment at Discharge (SUB–3/3a).

Comment: Some commenters requested clarification regarding visits that would be considered post-discharge follow-up. Some commenters requested clarification regarding whether telehealth visits, specifically audio-only telehealth visits, would be considered follow-up for purposes of the measure. A few commenters requested clarification regarding whether visits implemented through collaborative agreements with mental health providers would be considered follow-ups. These commenters further observed that including these visits would incentivize community partnerships. One commenter requested clarification regarding whether a visit to any HCP (including physicians, clinics, etc.) would be considered follow-up for purposes of the measure. This commenter further requested clarification regarding whether specific diagnosis codes would be required to be present on the follow-up claim.

Response: Regarding the request for clarification about the eligibility of telehealth visits for FAPH measure, both in-person and telehealth outpatient visits are acceptable, including audio-only visits. The FAPH numerator defines qualifying outpatient visits as outpatient visits, intensive outpatient encounters or partial hospitalizations that occur within 7 or 30 days of discharge and are defined by the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), and Uniform Billing (UB) Revenue codes, with or without the GT telehealth modifier. The CPT codes 99441, 99442, and 99443, which represent telephone E/M visits, are included in the list of codes to identify eligible outpatient visits. With respect to the request for clarification regarding collaborative agreements, the measure is agnostic to relationships between mental health providers, other providers, and health systems. The codes used to identify outpatient visits for the FAPH measure are not limited to mental health providers. The outpatient visit may be any outpatient visit, intensive outpatient encounter or partial hospitalization that occurs within 7 or 30 days of discharge as defined in section IV.E.3.b.(1). This visit must be paired with a qualifying ICD–10–CM diagnosis of mental illness or substance use disorder used to define the denominator.

Comment: One commenter observed that historical trending would no longer be available due to the transition from FUH to FAPH.

Response: We agree with the commenter that replacing FUH with FAPH would mean that historical trending would no longer be available. However, we believe that the benefits associated with the expanded patient population and the expanded provider types for follow-up appointments outweigh the loss of trend data.

After consideration of the public comments, we are finalizing the FAPH measure as proposed for the FY 2024 payment determination and subsequent years.

F. Removal or Retention of IPFQR Program Measures

1. Background

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38463 through 38465), we adopted considerations for removing or retaining measures within the IPFQR Program and criteria for determining when a measure is ''topped out.'' In the FY 2019 IPF PPS final rule (83 FR 38591 through 38593), we adopted one additional measure removal factor. We did not propose any changes to these removal factors, topped-out criteria, or retention factors and refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38463 through 38465) and the FY 2019 IPF PPS final rule (83 FR 38591 through 38593) for more information. We will continue to retain measures from each previous year's IPFQR Program measure set for subsequent years' measure sets, except when we specifically propose to remove or replace a measure. We will continue to use the notice-and-comment rulemaking

[150] American Psychiatric Association. Practice guideline for the treatment of patients with substance use disorders. 2010. *http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf.*

[151] *https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral.*

process to propose measures for removal or replacement, as we described upon adopting these factors in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38464 through 38465).

In the FY 2022 IPF PPS proposed rule we described that in our continual evaluation of the IPFQR Program measure set under our Meaningful Measures Framework and according to our measure removal and retention factors, we identified four measures that we believed were appropriate to propose removing from the IPFQR Program for the FY 2024 payment determination and subsequent years (86 FR 19507). Our discussion of these measures follows.

2. Measures Proposed for Removal in the FY 2022 IPF PPS Proposed Rule

a. Retention of the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) Measure Beginning With FY 2024 Payment Determination

We proposed to remove the Alcohol Use Brief Intervention Provided or Offered (SUB–2) and subset measure Alcohol Use Brief Intervention (SUB2a) collectively referred to as the SUB–2/2a measure from the IPFQR Program beginning with the FY 2024 payment determination under our measure removal Factor 8, ''The costs associated with a measure outweigh the benefit of its continued use in the program.'' We adopted the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) measure in the FY 2016 IPF PPS final rule (80 FR 46699 through 46701) because we believe it is important to address the common comorbidity of alcohol use among IPF patients. This measure requires facilities to chart-abstract measure data on a sample of IPF patient records, in accordance with established sampling policies (80 FR 46717 through 46719).

We have previously stated our intent to move away from chart-abstracted measures to reduce information collection burden in this and other CMS quality programs (78 FR 50808; 79 FR 50242; 80 FR 49693). When we adopted the SUB–2/2a measure to the IPFQR Program, the benefits of this measure were high because IPF performance was not consistent. Therefore, the measure provided a means of distinguishing IPF performance and incentivized facilities to improve rates of treatment for this common comorbidity. Between the FY 2018 payment determination (the first year that SUB–2/2a was included in the IPFQR Program measure set) and the FY 2019 payment determination, we saw substantial performance improvement on the SUB–2 measure (which is the portion of the SUB–2/2a measure that assesses whether the IPF provided or offered a brief intervention for alcohol use). However, for the FY 2019 and FY 2020 payment determinations, the rate of improvement has leveled off to consistently high performance, as indicated in Table 3. These data further show that at this time there is little room for improvement in the SUB 2 measure, and that the quality improvement benefits from the measure have greatly diminished.

As stated in the proposed rule, we continue to believe that alcohol use is an important comorbidity to address in the IPF setting, and that brief interventions are a key component of addressing this comorbidity. However, based on these data, we believe that most IPFs routinely offer alcohol use brief interventions, and that IPFs will continue to offer these interventions to patients, regardless of whether the SUB–2/2a measure is in the IPFQR Program measure set, because it has become an embedded part of their clinical workflows.

TABLE 3: – Performance Analysis for Alcohol Use Brief Intervention Provided or Offered (SUB-2)

Year	Mean	Median	75th percentile	90th percentile	Truncated Coefficient of Variation (TCV)
2016 (2018 Payment Determination)	66.96	77	96	100	0.49
2017 (2019 Payment Determination)	77.11	88	99	100	0.28
2018 (2020 Payment Determination)	79.49	91	100	100	0.25

In the proposed rule, we noted that while the measure does not meet our criteria for ''topped-out'' status because of the TCV higher than 0.1, we believe that this measure no longer meaningfully supports the program objectives of informing beneficiary choice and driving improvement in IPF interventions for alcohol use because it is no longer showing significant improvement in IPF performance (that is, in providing or offering alcohol use brief interventions). Furthermore, as we stated in the FY 2019 IPF PPS final rule, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program (83 FR 38592). For example, it may be costly for health care providers to maintain general administrative knowledge to report this measure. Additionally, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information.

Here, IPF information collection burden and related costs associated with reporting the SUB 2/2a measure to CMS are high because it is a chart-abstracted measure. Furthermore, CMS incurs costs associated with the program oversight of the measure for public display. As a result, we believe that the costs and burdens associated with this chart-abstracted measure outweigh the benefit of its continued use in the program.

Therefore, we proposed to remove the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) measure from the IPFQR Program beginning with the FY 2024 payment determination. We welcomed public comments on our proposal to remove the SUB–2/2a measure from the IPFQR Program.

We received the following comments on our proposal.

Comment: Many commenters supported our proposal to remove the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) measure. Some commenters agreed with our rationale that the costs of this measure outweigh the benefit of its continued use in the IPFQR Program. A few commenters recommended that CMS remove the measure immediately, rather than beginning with FY 2024 payment determination as proposed, to further reduce burden. One commenter agreed

that providers will continue these interventions after the measure has been removed. Another commenter also supported removal because the measure is no longer NQF endorsed and was not specified for this setting.

Response: We thank the commenters for their support. While we continue to believe that the performance on the SUB–2/2a measure in recent years indicates that IPFs routinely offer alcohol use brief interventions, we recognize that we will not be able to monitor whether IPFs continue these interventions if we remove this measure. We considered proposing to remove the measure sooner, but because data are currently being collected to report during CY 2022 to inform the FY 2023 payment determination, we proposed removing the measure following that payment determination, that is, for the FY 2024 payment determination.

The commenter is correct that the measure is no longer NQF endorsed and is not specified for the IPF setting. However, we continue to believe that this measure is appropriate for the IPF setting. We reiterate that we proposed to remove this measure because of the belief that the costs of the measure outweigh its continued benefits in the IPFQR Program, not because it is no longer NQF endorsed nor because it was not specified for this setting.

Comment: One commenter supported removal of the SUB–2/2a measure, but recommended development of more meaningful measures than SUB–2/2a and the Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Treatment at Discharge (SUB–3/3a) measure to address screening and intervention for substance use. Another commenter recommended that CMS consult with consumers to ascertain the benefits of measures in the IPFQR Program prior to proposing to remove any such measures, this commenter specifically recommended that CMS not finalize removal of the SUB–2/2a measure until fully considering input from consumers.

Response: We appreciate this commenter's input and are continually seeking to improve our measure set by developing more meaningful and less burdensome measures. As we evaluate areas appropriate for measure development, we will consider additional measures or measure concepts that more meaningfully address alcohol use disorder treatment for the IPF patient population.

In response to the request that we consult with consumers to ascertain the benefits of the measure, we note that we evaluate input from all stakeholders, including consumers, patients, caregivers, and patient advocacy groups that we receive in response to our proposals to adopt or remove measures from the IPFQR Program. As part of this process, we have reviewed input from consumers regarding the benefits of the measure and considered this input in our analysis.

Comment: Some commenters expressed concern about removing the measure. A few of these commenters stated that not all facilities perform well on the measure and, therefore, there is still room for improvement. One commenter stated that the COVID–19 pandemic has led to increased alcohol use and expressed the belief that removing the measure now is poorly timed.

Response: We note that we proposed to remove the measure because of the belief that the benefits of retaining it have lessened to the point that its costs outweigh those benefits, not because the measure is topped out. We agree with commenters that not all facilities perform uniformly well on the Alcohol Use Disorder Brief Intervention Provided or Offered and Alcohol Use Disorder Brief Intervention Provided (SUB–2/2a) measure.

We also agree that alcohol use has increased during the COVID–19 pandemic.[152] [153] [154] In our literature review regarding this comment, we also identified evidence that individuals with mental health and substance use conditions may be at an increased risk of COVID–19 complications and appropriate substance use disorder treatment may help mitigate these complications.[155] [156] To ensure that providers would continue to address alcohol use disorders among this patient population, we have maintained the Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol & Other Drug Use Treatment at Discharge (SUB–3/3a) measure. However, we note that a prominent model to ensure those with alcohol use disorder are identified and referred to treatment include both brief interventions and referrals.[157] Given the increased need for alcohol use brief interventions due to the pandemic, the current performance levels [158] (for FY 2018 payment determination, the mean performance nationally was approximately 80 percent of patients who screened positive for alcohol use disorder were offered or provided a brief intervention), and the importance of providing alcohol use brief interventions to improve the efficacy of alcohol use treatment at discharge, we believe that the benefits of retaining the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) measure are greater than we initially estimated in our proposal to remove this measure and that the measure should not be removed from the program at this time.

Comment: One commenter observed that this measure may be useful for future stratification based on race and ethnicity.

Response: We agree with the commenter that this measure may be useful for future stratification based on race and ethnicity. While we do not believe it would be appropriate to retain this measure specifically for the purpose of potential future stratification, we agree that this potential is another benefit of the measure that we had not considered in our previous analysis of the benefits versus the costs of retaining the measure.

Comment: One commenter observed that there are benefits to retaining this measure because IPFs and health systems use performance data on this measure as part of quality improvement initiatives to reduce alcohol use and that removal may affect these programs.

Response: We thank the commenter for this input. We note that IPFs are responsible for abstracting the data for this measure, so we believe that IPFs who use these data for their own quality improvement initiatives have access to these data regardless of whether the measure is in the IPFQR Program.

[152] Pollard et. al., Changes in Adult Alcohol Use and Consequences During the COVID–19 Pandemic in the US, JAMA Network Open, 2020;3(9):e2022942. doi:10.1001/jamanetworkopen.2020.22942.

[153] Alcohol Consumption Rises Sharply During Pandemic Shutdown; Heavy Drinking by Women Rises 41%, RAND, *https://www.rand.org/news/press/2020/09/29.html.*

[154] Nemani et al., Association of Psychiatric Disorders With Mortality Among Patients With COVID–19, JAMA *Psychiatry.* 2021;78(4):380–386. doi:10.1001/jamapsychiatry.2020.4442; COVID–19 and people at increased risk, CDC, *https://www.cdc.gov/drugoverdose/resources/covid-drugs-QA.html;* U. Saengow et. al.

[155] Wang et. al., COVID–19 risk and outcomes in patients with substance use disorders: Analyses from electronic health records in the United States, *Molecular Psychiatry* volume 26, pages 30–39 (2021), *https://www.nature.com/articles/s41380-020-00880-7.*

[156] Vai et. al., Mental disorders and risk of COVID–19-related mortality, hospitalisation, and intensive care unit admission: A systematic review and meta-analysis, Lancet Psychiatry, *https://www.thelancet.com/pdfs/journals/lanpsy/PIIS2215-0366(21)00232-7.pdf.*

[157] *https://www.samhsa.gov/sbirt; https://www.samhsa.gov/sbirt/coding-reimbursement.*

[158] For FY 2018 payment determination, the mean performance nationally was approximately 80 percent of patients who screened positive for alcohol use disorder were offered or provided a brief intervention.

However, we recognize that such IPFs and health systems would not have access to publicly reported data regarding other IPFs and that these data may be useful for baselining. Therefore, we agree that such IPF level and systemic programs to reduce alcohol use is a benefit to retaining the measure that we had not evaluated in our proposal to remove this measure.

Comment: One commenter observed that this measure is less burdensome than the newly proposed COVID–19 vaccination measure and therefore the commenter believes that removing this measure because the costs, especially the information collection burden, outweigh benefits is inconsistent.

Response: We evaluate measures on a case-by-case basis looking at the overall benefits of the measure versus the overall costs of the measure. Therefore, measures are not evaluated based on whether they are more or less burdensome than other measures. However, we now believe that the benefits of retaining this measure are greater than we had considered in our proposal to remove the measure from the IPFQR Program measure set.

After consideration of the public comments, we now believe that the benefits of retaining this measure, which include the potential for IPFs to continue improving performance on this measure, the importance of substance use interventions due to increased substance use during the COVID–19 pandemic, and this measure's potential influence on other quality improvement activities related to substance use are greater than we had considered in our proposal to remove the measure from the IPFQR Program measure set. Accordingly, we are not finalizing our proposal to remove the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) measure beginning with the FY 2024 payment determination. That is, we are retaining the Alcohol Use Disorder Brief Intervention Provided or Offered and Alcohol Use Disorder Brief Intervention Provided (SUB–2/2a) measure in the IPFQR Program measure set.

After consideration of the public comments, we are not finalizing our proposal to remove the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) measure beginning with the FY 2024 payment determination. That is, we are retaining the Alcohol Use Disorder Brief Intervention Provided or Offered and Alcohol Use Disorder Brief Intervention Provided (SUB–2/2a) measure in the IPFQR Program measure set.

b. Retention of the Tobacco Use Treatment Provided or Offered and Tobacco Treatment (TOB–2/2a) Measure Beginning With FY 2024 Payment Determination [159]

We proposed to remove the Tobacco Use Treatment Provided or Offered (TOB–2) and Treatment (TOB–2a), collectively referred to as the TOB–2/2a measure from the IPFQR Program beginning with the FY 2024 payment determination under our measure removal Factor 8, ''The costs associated with a measure outweigh the benefit of its continued use in the program.'' We adopted the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB–2/2a) measure in the FY 2015 IPF PPS final rule (79 FR 45971 through 45972) because we believe it is important to address the common comorbidity of tobacco use among IPF patients. Like SUB–2/2a described in the previous subsection, this measure requires facilities to chart-abstract measure data on a sample of IPF patient records, in accordance with established sampling policies (80 FR 46717 through 46719).

When we introduced the TOB–2/2a measure to the IPFQR Program, the benefits of this measure were high, because IPF performance was not consistent and therefore the measure provided a means of distinguishing IPF performance and incentivized facilities to improve rates of treatment for this common comorbidity. Between the FY 2017 payment determination (the first year that TOB–2/2a was included in the IPFQR Program's measure set) and the FY 2019 payment determination we saw substantial performance improvement on TOB–2. However, between the FY 2019 and FY 2020 payment determinations, that improvement has leveled off to consistently high performance, as indicated in Table 4. These data further show that currently there is little room for improvement in the TOB–2 measure, and that the quality improvement benefits from the measure have greatly diminished. We continue to believe that tobacco use is an important comorbidity to address in the IPF setting, and that brief interventions are a key component of addressing this comorbidity. However, based on these data, we stated in the proposed rule that we believe that most IPFs routinely offer tobacco use brief interventions, and that IPFs will continue to offer these interventions to patients, regardless of whether the TOB–2/2a measure is in the IPFQR Program measure set, because it has become an embedded part of their clinical workflows.

TABLE 4: Performance Analysis for Tobacco Use Treatment Provided or Offered (TOB-2)

Year	Mean	Median	75th percentile	90th percentile	Truncated Coefficient of Variation (TCV)
2015 (2017 Payment Determination)	63.83	71.5	91	99	0.49
2016 (2018 Payment Determination)	74.72	84	95	100	0.28
2017 (2019 Payment Determination)	79.04	88	97	100	0.22
2018 (2020 Payment Determination)	79.08	88	98	100	0.22

While the measure does not meet our criteria for ''topped-out'' status because of the TCV higher than 0.1, we believe that this measure no longer meaningfully supports the program objectives of informing beneficiary choice and driving improvement in IPF interventions for tobacco use because it is no longer showing significant improvement in IPF performance (that is, in providing or offering tobacco use brief interventions). Furthermore, as we

[159] We note that the proposed rule incorrectly referred to this measure as the Tobacco Use Brief Intervention Provided or Offered and Tobacco Use Brief Intervention (TOB–2/2a) measure, we have corrected it here and throughout this final rule.

stated in the FY 2019 IPF PPS final rule, costs are multi-faceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program (83 FR 38592). For example, it may be costly for health care providers to maintain general administrative knowledge to report this measure. Additionally, CMS must expend resources in maintaining information collection systems, analyzing reported data, and providing public reporting of the collected information. Here, IPF information collection burden and related costs associated with reporting this measure to CMS are high because the measure is a chart-abstracted measure. Furthermore, CMS incurs costs associated with the program oversight of the measure for public display. As a result, we believe that the costs and burdens associated with this chart-abstracted measure outweigh the benefit of its continued use in the program.

Therefore, we proposed to remove the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB–2/2a) measure from the IPFQR Program beginning with the FY 2024 payment determination. We welcomed public comments on our proposal to remove the TOB–2/2a measure from the IPFQR Program.

We received the following comments on our proposal.

Comment: Many commenters supported our proposal to remove the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB–2/2a) measure. Some of these commenters agreed with our rationale that the costs of this measure outweigh the benefits of its continued use in the IPFQR Program. Several commenters recommended removing the measure immediately, rather than beginning with FY 2024 payment determination as proposed, to further reduce burden. One commenter agreed that providers will continue offering this intervention even if it is not being measured. Another commenter further expressed that removal is appropriate because the measure is no longer NQF endorsed and is not specified for this setting.

Response: We thank the commenters for their support. We considered proposing to remove the measure sooner, but because data are currently being collected to report during CY 2022 to inform the FY 2023 payment determination, we proposed to remove the measure following that payment determination, that is, for the FY 2024 payment determination. While we continue to believe that the performance on the TOB–2/2a measure in recent years indicates that IPFs routinely offer tobacco use cessation interventions during the inpatient stay, we recognize that we will not be able to monitor whether IPFs continue these interventions if we remove this measure. The commenter is correct that the measure is no longer NQF endorsed and is not specified for the IPF setting. We reiterate that we proposed to remove this measure because of the belief that the costs of the measure outweigh its continued benefits in the IPFQR Program not because it is no longer NQF endorsed nor because it was not specified for this setting and we continue to believe that this measure is appropriate for the IPF setting.

Comment: One commenter expressed the belief that progress in electronic reporting systems leads to lower burden for reporting this measure. This commenter expressed the belief that this reduced burden should factor into the consideration of whether costs outweigh benefits and recommended that CMS retain this measure.

Response: We thank the commenter for this feedback. However, we note that because this is a chart-abstracted measure, we do not believe access to electronic reporting systems will significantly impact the burden of collecting and reporting this measure for most IPFs.

Comment: One commenter supported removal of the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment Provided (TOB–2/2a) measure, but recommended development of more meaningful measures than TOB–2/2a and Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB–3/3a) to address screening and intervention for tobacco use. One commenter recommended that CMS seek consumer input on the benefit of measures before proposing to remove them.

Response: We appreciate this commenter's input and are continually seeking to improve our measure set by developing more meaningful and less burdensome measures. As we evaluate areas appropriate for measure development, we will consider additional measures or measure concepts that more meaningfully address tobacco use treatment for the IPF patient population.

In response to the request that we consult with consumers to ascertain the benefits of the measure, we note that we evaluate input from all stakeholders, including consumers, patients, caregivers, and patient advocacy groups that we receive in response to our proposals to adopt or remove measures from the IPFQR Program. As part of this process, we have reviewed input from consumers regarding the benefits of the measure and considered this input in our analysis.

Comment: Some commenters expressed concern about removing the TOB–2/2a measure from the IPFQR Program measure set. Some of these commenters expressed that there continues to be significant room for improvement in providing interventions. One commenter specifically observed that the measure is not topped out. A few commenters observed that the proposed removal is poorly timed due to the increase in tobacco use during the COVID–19 pandemic. Another commenter cited evidence supporting the benefit of brief interventions as part of a comprehensive program to address topped out.

We agree with commenters that not all facilities perform uniformly well on the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment Provided (TOB–2/2a) measure. We also agree with the commenter's observation that tobacco use has increased during the COVID–19 pandemic.[160] In our literature review, we also identified evidence that individuals who use tobacco may be at an increased risk of COVID–19 complications and tobacco use treatment may help mitigate these complications.[161] To ensure that providers would continue to address tobacco use among this patient population, we maintained the Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment Provided at Discharge (TOB–3/3a). However, we agree with the commenter who expressed that these interventions are most effective as part of a comprehensive tobacco treatment program. Given the increased need for tobacco use interventions due to the COVID–19 pandemic, that this measure is not topped out and there is room for improvement across facilities,[162] and the importance of providing tobacco use treatment during the inpatient stay to improve the efficacy of tobacco use treatment at discharge, we believe that the benefits of retaining the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment Provided (TOB–2/2a) measure are greater than we

[160] Giovenco et. al., Multi-level drivers of tobacco use and purchasing behaviors during COVID–19 ''lockdown'': A qualitative study in the United States, International Journal of Drug Policy, Volume 94, August 2021, 103175.

[161] *https://www.who.int/news/item/11-05-2020-who-statement-tobacco-use-and-covid-19.*

[162] For the FY 2018 payment determination, the mean performance nationally was approximately 79 percent of patients who screened positive for tobacco use were provided or offered treatment while inpatients.

estimated in our proposal to remove this measure and that the measure should not be removed from the program at this time.

Comment: Many commenters opposed removal of the measure because of the clinical importance of treating tobacco use in the IPF patient population. Many of these commenters observed that tobacco use is undertreated. Some of these commenters referenced CDC data stating that only 48.9 percent of mental health treatment facilities reported screening patients for tobacco use. Some commenters pointed to this statistic and expressed concern that without measures related to tobacco use treatment this care may no longer be provided in IPFs. These commenters observed that tobacco use is nearly three times more prevalent in people with serious psychological distress than in those without. Some of these commenters observed that this discrepancy contributes to a shorter life expectancy for patients with mental illness who smoke. These commenters expressed the belief that the potential to increase patient life expectancy and quality of life outweighs the costs of reporting the measure. A few of these commenters observed there are high costs associated with treating tobacco associated illness and that these costs could be significantly reduced by increased screening, intervention, and treatment.

Some commenters stated that the 2020 Surgeon General's report specifically stated that tobacco dependence treatment is applicable to the behavioral health setting. One commenter observed that brief interventions are part of the ''Treating Tobacco Use and Dependence Clinical Practice Guidelines.'' One commenter stated that behavioral health patients often have limited interaction with the healthcare system and therefore the commenter believes that it is important to use these interactions to drive health behaviors.

Response: We agree with commenters that providing or offering tobacco use brief intervention within the IPF setting is a valuable intervention because of the prevalence of this comorbidity within this patient population and because of the ability of this intervention to facilitate quitting tobacco use. We further agree that brief interventions are part of clinical guidelines and are appropriate to provide to patients receiving care for behavioral health conditions. We note that the tobacco screening statistics cited by commenters refer to all behavioral health and substance use treatment facilities, whereas the IPFQR Program only requires reporting on treatment provided by IPFs that receive Medicare payment under the IPF PPS, therefore the statistics cited by commenters do not directly reflect care provided by IPFs.[163] However, we acknowledge that the low performance on tobacco use screening in the behavioral health setting does indicate that tobacco screening and treatment performance may lapse in the IPF setting without measures to address this topic, and that the inpatient setting may be a uniquely opportune setting for providing tobacco cessation interventions to some patients due to limited access to or utilization of the healthcare system. We also agree with commenters that providing tobacco use brief interventions has the potential to increase patient life expectancy and quality of life while reducing healthcare costs associated with treating tobacco associated illness. Given the importance of tobacco use interventions in extending life expectancy and improving quality of life, the concern regarding potential reduction in performance if measures are removed (as demonstrated by CDC data that show that the provision of brief intervention for tobacco use cessation is not the current standard of care across behavioral health settings as only 48.9 percent of mental health treatment facilities report screening patients for tobacco use), and the room for improvement in the current performance levels, we believe that the benefits of retaining the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment Provided (TOB–2/2a) measure are greater than we estimated in our proposal to remove this measure and that the measure should not be removed from the program at this time.

Comment: One commenter observed that there are health equity concerns regarding tobacco use and recommended that CMS retain this measure for future stratification based on race and ethnicity.

Response: We agree with the commenter that this measure may be useful for future stratification based on race and ethnicity. While we do not believe it would be appropriate to retain this measure specifically for the purpose of potential future stratification, we agree that this potential is another benefit of the measure that we had not considered in our previous analysis of the benefits versus the costs of retaining the measure.

Comment: One commenter observed that there are benefits to retaining this measure because IPFs and health systems use performance data on this measure as part of quality improvement initiatives to reduce tobacco use and that measure removal may affect those programs.

Response: We thank the commenter for this feedback. We note that IPFs are responsible for abstracting the data for this measure, so we believe that IPFs who use these data for their own quality improvement initiatives have access to these data regardless of whether the measure is in the IPFQR Program. However, we recognize that such IPFs and health systems would not have access to publicly reported data regarding other IPFs and that these data may be useful for baselining. Therefore, we agree that such IPF level and systemic programs to reduce tobacco use is a benefit to retaining the measure that we had not evaluated in our proposal to remove this measure.

Comment: Many commenters expressed the belief that without this measure IPFs would not continue to provide tobacco use brief interventions. Some commenters expressed concern that removing this measure would reduce providers' incentive to offer brief interventions. These commenters further observed that it would be difficult to determine whether IPFs continue to offer this intervention as the ability to track that depends on the continued collection of this measure. Some commenters further expressed concern that CMS policies drive the behavior of other payers and without this measure the healthcare system may lose focus on tobacco treatment for patients with behavioral health disorders.

Response: We understand commenters' concern regarding the potential for IPFs and other payers to no longer focus on tobacco treatment without the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB–2/2a) quality measure in the IPFQR Program and we agree that ensuring continuing focus on tobacco use treatment in this setting is a benefit of retaining this measure in the IPFQR program. Additionally, we agree that tracking whether IPFs continue to offer this intervention is a benefit of retaining the measure in the IPFQR program measure set.

Comment: One commenter observed that the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB–2/2a) measure is not as burdensome as the newly proposed COVID–19 vaccination measure and therefore the commenter believes that removing this measure because the costs, especially the information

[163] *https://www.cdc.gov/mmwr/volumes/67/wr/mm6718a3.htm.*

collection burden, outweigh benefits is inconsistent.

Response: We evaluate measures on a case-by-case basis looking at the overall benefits of the measure versus the overall costs of the measure. Therefore, measures are not evaluated based on whether they are more or less burdensome than other measures. However, we now believe that the benefits of retaining this measure are greater than we had considered in our proposal to remove the measure from the IPFQR Program measure set.

After consideration of the public comments, we now believe that the benefits of retaining this measure, which include the potential for IPFs to continue improving performance on this measure, the importance of tobacco use interventions due to increased tobacco use during the COVID–19 pandemic, and this measure's potential influence on other quality improvement activities related to tobacco use, are greater than we had considered in our proposal to remove the measure from the IPFQR Program measure set. Accordingly, we are not finalizing our proposal to remove the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB–2/2a) measure beginning with the FY 2024 payment determination. That is, we are retaining the Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB–2/2a) measure in the IPFQR Program measure set.

c. Removal of the Timely Transmission of Transition Record (Discharges From an Inpatient Facility to Home/Self Care or Any Other Site of Care) Measure Beginning With FY 2024 Payment Determination

We proposed to remove the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure from the IPFQR Program beginning with the FY 2024 payment determination under our measure removal Factor 8, ''The costs associated with a measure outweigh the benefit of its continued use in the program.''

We adopted the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure in the FY 2016 IPF PPS final rule (80 FR 46706 through 46709) because more timely communication of vital information regarding the inpatient hospitalization results in better care, reduction of systemic medical errors, and improved patient outcomes. The Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure builds on the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure, which requires facilities to provide a discharge record with 11 specified elements to patients at discharge.

We continue to believe that the 11 elements required by the Transition Record with Specified Elements measure provide meaningful information about the quality of care provided by IPFs, and we therefore did not propose to remove that measure from the IPFQR Program. However, we believe that the benefits of requiring facilities to transmit the discharge record with 11 specified elements to the next level care provided within 24 hours, as required by the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure, have been reduced. Reporting this measure requires facilities to chart-abstract measure data on a sample of IPF patient records, in accordance with established sampling policies (80 FR 46717 through 46719). On May 1, 2020, we updated the Conditions of Participation (CoPs) for IPFs participating in the Medicare program in the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, and Health Care Providers final rule (85 FR 25588).

In the May 1, 2020 update to the CoPs, we adopted a requirement for psychiatric hospitals that possess EHR or other administrative systems with the technical capacity to generate information for electronic patient event notifications to send electronic patient event notifications of a patient's admission, discharge, transfer to another health care facility or to another community provider, or combination of patient events at the time of a patient's discharge or transfer. Because these updated CoP requirements overlap with, but are not the same as, the requirements for the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure (which requires transmission of a discharge record with 11 specified elements to the next level care provider within 24 hours of the patient's discharge rather that requiring notification regarding the patient's inpatient stay to be transmitted at discharge), we believe that the adoption of these updated CoPs increases the costs of the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure while decreasing its benefit. Specifically, we believe that the costs of this measure are increased because facilities to which the new CoPs apply (that is, facilities that possess EHR or other administrative systems with the technical capacity to generate information for electronic patient event notifications as defined in the CoP) could bear increased cost if they separately implement the patient event notifications meeting both the criteria for the updated CoPs and the capacity to share a transition record that meets the requirements of our measure. We noted that the updated CoPs do not include the level of detail regarding data to be transferred at discharge that our Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure requires. While the set of information in the CoP notification policy is a minimal set of information, we believe that it would continue to be appropriate for providers to transmit the transition record that they will continue to be providing to patients under our Transition Record Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure, we further note that the CoPs referenced in the proposed rule are not an exhaustive list of data transfer requirements.

We believe the different requirements regarding both timeliness of notification and contents of notification could lead some providers to send two separate discharge notifications to meet the separate requirements. Further, we believe that the benefits of the measure are reduced because all facilities to which the new CoPs apply will be sending patient discharge information to the next level of care provider as required by the CoPs. Therefore, the benefits of this measure are reduced because it is less likely to ensure that these facilities provide patient discharge information to the next level care provider, and it is less likely to provide information to help consumers differentiate quality between facilities. While these updated CoPs do not directly address transmission of patient event notifications for facilities that do not possess EHR systems with the capacity to generate information for electronic patient event notifications,

such facilities should continue to transmit data using their existing infrastructure and timelines.

Because we believe that the costs are now increased and the benefits are now reduced, we believe that the costs and burdens associated with this chart-abstracted measure outweigh the benefit of its continued use in the IPFQR Program.

Therefore, we proposed to remove the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure from the IPFQR Program beginning with the FY 2024 payment determination. We welcomed public comments on our proposal to remove the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure from the IPFQR Program.

We received the following comments on our proposal.

Comment: Many commenters supported the removal of the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure. One commenter recommended immediate removal to further reduce burden. Another commenter expressed that this measure was not developed for IPFs and has been difficult to report because the specifications are not appropriate for the setting. Another commenter further noted that the measure is no longer NQF endorsed.

Response: We thank the commenters for their support. We considered removing the measure sooner, but because data are currently being collected to report during CY 2022 to inform the FY 2023 payment determination, we decided to propose removing the measure following that payment determination, therefore we proposed removal for the FY 2024 payment determination. The commenter is correct that the measure is no longer NQF endorsed and is not specified for the IPF setting; however we continue to believe that this measure is appropriate for the setting. We reiterate that removal of the measure is because we believe that the costs of the measure outweigh its continued benefits in the IPFQR Program.

Comment: Some commenters observed that the updated CoPs will not apply to many IPFs, especially freestanding IPFs that are not part of larger healthcare facilities, because IPFs were excluded from Meaningful Use incentives and therefore often do not have electronic data systems capable of meeting the standards in the updated CoPs.

Response: We acknowledge that there are a large number of IPFs that do not possess EHR systems with the technical capacity to generate information for electronic patient event notifications of a patient's admission, discharge, or transfer to another health care facility or to another community provider, or combination of patient events at the time of a patient's discharge or transfer. However, for those IPFs that can meet these requirements, we believe that retaining the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure could be burdensome depending on how facilities implement new requirements. Therefore, while for some IPFs the benefits may outweigh the costs, overall, for the IPFQR Program we believe the costs now outweigh the benefits. We reiterate that for IPFs that do not possess EHR systems with the capacity to generate information for patient event notifications as defined in the CoP regulations set forth at 42 CFR 482.24(d), such facilities should continue to transmit data using their existing infrastructure and timelines.

Comment: A few commenters recommended that CMS retain the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure. Some of these commenters believe that the measure's benefits are more significant than the burden. One commenter recommended that CMS seek consumer input on benefits prior to proposing measures for removal.

Response: We reiterate that we do not believe that the benefits of transmitting the transition record within 24 hours of discharge are reduced, or are lower than the costs of reporting; we believe that given the updates to the CoPs which overlap with this measure the benefits of retaining the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure are no longer sufficient to justify retention. We used the notice and comment rulemaking process to solicit input on measure benefits from all stakeholders, including consumers.

After consideration of the public comments, we are finalizing our proposal to remove the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure beginning with the FY 2024 payment determination.

d. Removal of the Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) Beginning With FY 2024 Payment Determination

In the FY 2022 IPF PPS proposed rule we stated that if we finalize adoption of the Follow-Up After Psychiatric Hospitalization measure described in section IV.E.3, we believed that our current measure removal Factor 3 would apply to the existing Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure (86 FR 19510). Measure removal Factor 3 applies when a ''measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topics.'' We adopted removal factor 3 in the FY 2017 IPPS/LTCH PPS final rule (82 FR 38463 through 38465). The FAPH measure expands the patient population from patients with mental illness to also include patients with primary SUD diagnoses while addressing the same important aspect of care transitions. Because this FAPH measure uses the same methodology to address the same element of care for a broader patient population than the FUH measure, we believe that it is more broadly applicable across populations.

Therefore, we proposed to remove the FUH measure under measure removal Factor 3 only if we finalized our proposal to adopt of the FAPH measure. We noted that if we did not adopt the FAPH measure, we would retain the FUH measure because we believe this measure addresses an important clinical topic. We welcomed public comments on our proposal to remove FUH if we were to adopt FAPH.

We received the following comments on our proposal.

Comment: Many commenters supported removal of this measure. Some commenters specifically noted that FAPH is more broadly applicable and therefore preferable.

Response: We thank these commenters for their support.

Comment: One commenter does not support either the FUH measure or the FAPH measure due to the belief that measures of follow-up after hospitalization are not appropriate for the IPFQR Program and recommended removing the FUH measure but not adopting the FAPH measure.

Response: For the reasons set forth in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50894 through 50895) and the FY 2022 IPF PPS proposed rule in our proposal to adopt the FAPH measure (86 FR 19504 through 19507), we believe that a measure of follow-after

hospitalization is an important concept for the inpatient psychiatric setting. Therefore, we do not believe it would be appropriate to remove the FUH measure without adopting the FAPH measure.

Comment: One commenter observed that the FUH measure is an NQF-endorsed measure, while the NQF declined to endorse the FAPH measure. This commenter recommended retaining the FUH measure because it is endorsed.

Response: The commenter is correct that the FUH measure is NQF endorsed and that the NQF declined to endorse the FAPH measure. However, as discussed in the FY 2022 IPF PPS proposed rule, the FUH measure does not apply to as broad a patient population, nor does it allow for follow-up care to be provided by as many provider types (86 FR 19507). Further, for the reasons we discussed in the FY 2022 IPF PPS proposed rule, we believe the exception under section 1886(s)(4)(D)(ii) of the Act applies (86 FR 19507). Because the FAPH measure is a more broadly applicable measure we believe it is appropriate for adoption into the IPFQR Program.

After consideration of the public comments, we are finalizing our proposal to remove Follow-Up After Hospitalization for Mental Illness (FUH, NQF #0576) measure beginning with the FY 2024 payment determination.

G. Summary of IPFQR Program Measures

1. IPFQR Program Measures for the FY 2023 Payment Determination and Subsequent Years

There are 14 previously finalized measures for the FY 2023 payment determination and subsequent years. In this final rule, we are adopting one measure for the FY 2023 payment determination and subsequent years. The 15 measures which will be in the program are shown in Table 5.

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TABLE 5: IPFQR Program Measure Set for the FY 2023 Payment Determination and Subsequent Years with Finalized Measure Adoption

NQF #	Measure ID	Measure
0640	HBIPS-2	Hours of Physical Restraint Use
0641	HBIPS-3	Hours of Seclusion Use
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification
0576	FUH	Follow-Up After Hospitalization for Mental Illness
N/A*	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention
N/A*	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge
N/A*	TOB-2 and TOB-2a	Tobacco Use Treatment Provided or Offered and TOB-2a Tobacco Use Treatment
N/A*	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge
1659	IMM-2	Influenza Immunization
N/A*	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)
N/A*	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or any Other Site of Care)
N/A	N/A	Screening for Metabolic Disorders
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric Discharge
TBD	COVID HCP	COVID-19 Healthcare Personnel (HCP) Vaccination Measure

* Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

2. IPFQR Program Measures for the FY 2024 Payment Determination and Subsequent Years

There are 14 previously finalized measures for the FY 2024 payment determination and subsequent years. In this final rule, we are adopting one measure for the FY 2023 payment determination and subsequent years. Additionally, we are finalizing our proposal to remove one measure and replace one measure for the FY 2024 payment determination and subsequent years. We are not finalizing our proposals to remove two measures for the FY 2024 payment determination and subsequent years. The 14 measures which will be in the program for FY 2024 payment determination and subsequent years are shown in Table 6.

TABLE 6: IPFQR Program Measure Set for the FY 2024 Payment Determination and Subsequent Years

NQF #	Measure ID	Measure
0640	HBIPS-2	Hours of Physical Restraint Use
0641	HBIPS-3	Hours of Seclusion Use
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification
N/A	FAPH	Follow-Up After Psychiatric Hospitalization
1659	IMM-2	Influenza Immunization
N/A*	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention
N/A*	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge
N/A*	TOB-2 and TOB-2a	Tobacco Use Treatment Provided or Offered and TOB-2a Tobacco Use Treatment
N/A*	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge
N/A*	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)
N/A	N/A	Screening for Metabolic Disorders
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric Discharge
TBD	COVID HCP	COVID-19 Healthcare Personnel (HCP) Vaccination Measure

* Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

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H. Considerations for Future Measure Topics

As we have previously indicated, 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 IPF setting (79 FR 45974 through 45975). Therefore, through future rulemaking, we intend to propose new measures for development or adoption that will help further our goals of achieving better healthcare and improved health for individuals who obtain inpatient psychiatric services through the widespread dissemination and use of quality information. In 2017, we introduced the Meaningful Measures Framework as a tool to foster operational efficiencies and reduce costs including collection and reporting burden while producing quality measurement that is more focused on meaningful outcomes (83 FR 38591). As we continue to evolve the Meaningful Measures Framework, we have stated that we intend to better address health care priorities and gaps, emphasize digital quality measurement, and promote patient perspectives.[164] As we work to align the IPFQR Program's measure set with these priorities, we have identified the following areas that we believe are important to stakeholders, but which are not covered in the current IPFQR Program measure set: Patient Experience of Care, Functional Outcomes Measurement, and digital measures. As described in the following subsections, we sought public comment on each of these topics and other future measure considerations which stakeholders believe are important.

We received the following public comment on measure considerations which stakeholders believe are important.

Comments: Many commenters suggested measure areas that they believe are important for IPFs. These areas were: (1) Suicide evaluation and reduction; (2) patient experience; (3) patient improvement; (4) clinical processes that impact significant numbers of patients in important clinical domains; (5) patient and workforce safety; (6) caregiver engagement; (7) safety culture; (8) workforce engagement, (9) immunization status; (10) measures that more rigorously capture data on tobacco and substance use interventions; and (11) discharge planning measures. Some commenters recommended developing improved discharge planning measures. One commenter recommended that CMS ensure that the role of nurse practitioners is included in measures. One commenter recommend that CMS engage with patients and their caregivers to identify topics they find important. Another commenter recommended that CMS seek industry input on measure considerations.

Response: We thank these commenters for this input. We will consider these recommendations as we seek to develop a more comprehensive measure set for the IPFQR Program.

1. Patient Experience of Care Data Collection Instrument

When we finalized removal of the Assessment of Patient Experience of

[164] *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

Care attestation measure in the FY 2019 IPF PPS final rule (83 FR 38596) we stated that we believed we had collected sufficient information to inform development of a patient experience of care measure that would capture data on the results of such a survey. In the FY 2020 IPF PPS proposed rule (84 FR 16986 through 16987), we solicited input on how providers had implemented the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey in their facilities. We also sought public comment on other potential surveys that commenters believed would be appropriate to adopt for the IPFQR Program. We received many comments on this subject, and many of these comments expressed that there is not one survey used predominantly across IPFs (84 FR 38467). Additional commenters expressed concerns that the HCAHPS survey may not be appropriate for the IPF setting because it does not include some of the unique aspects of inpatient psychiatric care including, group therapy, non-physician providers, and involuntary admissions. While we did not solicit public comment on this issue in the FY 2021 IPF PPS proposed rule, we received many comments addressing this issue (85 FR 47043). We continue to seek to identify a minimally burdensome patient experience of care instrument that would be appropriate for the IPF setting. Therefore, in the FY 2022 IPF PPS proposed rule (86 FR 19511 through 19512) we sought public comment on instruments currently in use in the IPF setting, input on whether the HCAHPS survey may be appropriate for this setting, and information on how facilities that currently use the HCAHPS survey have addressed challenges with using this survey within this setting (that is, concerns regarding unique aspects of inpatient psychiatric care).

We received the following comments in response to our request.

Comment: Many commenters expressed support for development of a uniform patient experience of care measure because this is a gap in the IPFQR measure set. Many commenters expressed that there is currently no patient experience of care measure in the IPFQR Program and expressed the belief that such a survey could improve provider accountability, show respect for patients, and drive quality improvement. Some commenters observed that patients should be given the opportunity to share their experiences regardless of diagnosis. One commenter observed that evaluations of patient experience of care can be a driver of health equity.

Many commenters shared personal or family experiences in IPFs and indicated that being able to share such experiences in a formal survey would allow patients and caregivers to have a voice, provide valuable feedback, feel respected, provide information for quality improvements, and inform other potential patients. One commenter observed that allowing proxies would be valuable. Some commenters observed that not collecting patient experience of care data leads to the perception that patients' opinions are not valid and expressed the concern that this message may further objectify and traumatize a vulnerable patient population in a stressful and potentially stigmatizing situation (that is, psychiatric hospitalization). Other commenters expressed that not collecting such data normalizes poor treatment of psychiatric patients. Some commenters observed that patients with psychiatric illness are not less likely to be competent to express their experience of care than patients with other acute care needs.

Many commenters recommended that CMS identify a minimum set of items to include in surveys, as opposed to requiring a specific survey. These commenters observed that the net promoter score (NPS) used by the National Health Service in the UK may be a good model to consider. Some commenters observed that many facilities have designed their own surveys tailored to their patient populations (for example, pediatric patients, involuntarily admitted, etc.) and that it would be preferable for these facilities to add questions to meet a minimum set rather than to replace their surveys.

Many commenters expressed that they do not support HCAHPS for the IPF setting. These commenters expressed that (1) the HCAHPS was developed for patients with non-psych primary diagnoses and not for behavioral health diagnoses therefore the questions on HCAHPS do not address patients' top concerns regarding IPF care; (2) the survey protocols which allow for administration of the survey up to 6 weeks post-discharge may negatively impact completion rates due to the transient nature of the patient population; (3) the protocols do not have a web-interface for survey administration nor email or text survey invites; and (4) HCAHPS does not account for involuntary admissions. Some commenters also expressed concern that HCAHPS is not validated, nor has it been through psychometric testing in this setting. Some commenters observed the HCAHPS survey is due for a redesign and observed that CMS could potentially address concerns with the HCAHPS survey as part of the intended redesign. Other commenters recommended that CMS develop a survey unique to this setting that addresses aspects of care specific to the setting (such as group therapy, treatment by therapists, involuntary admission, medication treatment, consistency of treatment). One commenter recommended that CMS collaborate with AHRQ in survey design and development. Some commenters recommended that CMS ensure proper risk adjustment because patient characteristic can affect patient experience.

Some commenters observed that the questions on HCAHPS apply to IPF patients and recommended that CMS test HCAHPS for this setting. A few of these commenters observed that using the same measure across settings would improve behavioral health parity, facility comparison, and reduce burden for facilities that are distinct part units in acute care hospitals that use HCAHPS. A few commenters expressed concern that excluding psychiatric patients from HCAHPS is discrimination based on a disability which, because of the benefits derived from patient experience surveys, denies patients with psychiatric diagnoses equal treatment. Other commenters observed that minimizing burden is not a factor in establishing patient experience of care measures in other settings and that therefore it should not be a consideration in this setting. Some commenters observed that CMS has requested and received input on this subject for several years and requested a specific plan of action.

A few commenters recommended that CMS collaborate with IPFs to determine how to assess patients' experience of care, several commenters recommended that CMS establish a technical expert panel (TEP) with IPF members.

One commenter recommended that CMS reintroduce the attestation measure until a solution for assessing patient experience of care is identified.

Response: We thank these commenters for their input. We agree that Patient Experience of Care is a gap in the current IPFQR Program measure set and we agree with commenters that adoption of such a measure would be a meaningful step towards ensuring that patients have a voice regarding the care they receive. We appreciate the input from patients and their caregivers explaining how meaningful such a measure would be for these stakeholders. We intend to use the feedback provided here and in past requests to identify the most appropriate

path forward towards adopting such a measure as soon as possible.

2. Functional Outcomes Instrument for Use in a Patient Reported Outcomes Measure

When we introduced the Meaningful Measures Framework, we stated that we wanted to focus on meaningful outcomes (83 FR 38591). As we have assessed the IPFQR Program measure set against the Meaningful Measures Framework, we have identified functional outcomes as a potential gap area in the IPFQR Program's measure set. Therefore, we are evaluating whether a patient reported outcomes measure that assesses functional outcomes, such as global functioning, interpersonal problems, psychotic symptoms, alcohol or drug use, emotional lability, and self-harm, would be an appropriate measure to include in the IPFQR program measure set. If we were to develop such a measure, we would develop a measure that compares a patient's responses to a standardized functional outcomes assessment instrument at admission with the patient's results on the same assessment instrument at discharge. We sought public comment on the value of such a measure in the IPFQR program measure set, what would be an appropriate functional outcome assessment instrument to use in the potential development of such a measure, and any additional topics or concepts stakeholders believe would be appropriate for patient reported outcomes measures.

We received the following comments in response to our request.

Comment: Many commenters supported the concept of a functional outcomes measure and recommended preceding development of such a measure with an attestation measure which asks IPFs whether they use an assessment, and if so which one.

Some commenters expressed concern regarding outcome measures in this setting. One commenter specifically observed that short lengths of stay often lead to minimal progress on outcomes. One commenter mentioned the lack of endorsed, public domain outcome measures for this setting.

A few commenters recommended that CMS convene a technical expert panel (TEP) on patient reported outcomes for this setting.

One commenter uses PHQ–9 to assess outcomes. Another commenter uses BASIS–32 or CABA–Y depending on the patient population.

Response: We thank the commenters for their input and will consider this feedback as we continue to evaluate a functional outcomes measure for this setting.

3. Measures for Electronic Data Reporting

As we seek to improve digital measurement across our quality reporting and value-based payment programs, we are considering measures both within and appropriate to adopt for the IPFQR Program measure set that would be appropriate for digital data collection. In our assessment of the current measure set, we identified the Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure as a potential option for digital data collection. We sought stakeholder input on the current data collection burden associated with this measure, concerns regarding potential electronic specification and data collection for this measure, and other measures that may be appropriate for electronic data collection, either those currently in the IPFQR Program measure set, or those that we could adopt in the future.

We received the following comments in response to our request.

Comment: Several commenters supported transitioning the IPFQR Program to electronic reporting.

Many commenters observed that IPFs have not received Federal incentives to support EHR adoption and expressed the belief that electronic data reporting without such funding is premature.

Some commenters observed that the Transition Record measure is a complicated measure for e-specification. Some of these commenters noted that this measure requires a large number of data elements, some of which are not available in structured fields. One commenter recommended considering Metabolic Screening or Influenza Immunization for electronic specification as these measures have fewer data elements and those elements are available in structured fields. Another commenter observed that e-specification of existing chart measures often does not provide comparable results.

Response: We thank commenters for this input. We acknowledge that IPFs were not eligible to receive prior Federal incentives to support EHR adoption and will consider this and other input as we seek to transition the IPFQR Program to electronic data reporting.

I. Public Display and Review Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53654), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57248 through 57249) for discussion of our previously finalized public display and review requirements. We did not propose any changes to these requirements.

J. Form, Manner, and Timing of Quality Data Submission for the FY 2022 Payment Determination and Subsequent Years

1. Procedural Requirements for the FY 2023 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53655), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50898 through 50899), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38471 through 38472) for our previously finalized procedural requirements. In this final rule, we are finalizing our proposal to use the term ''QualityNet security official'' instead of ''QualityNet system administrator,'' finalizing our proposal to revise § 412.434(b)(3) by replacing the term ''QualityNet system administrator'' with the term ''QualityNet security official,'' and clarifying our policy under the previously finalized requirement that hospitals ''[i]dentify a QualityNet Administrator who follows the registration process located on the QualityNet website'' (77 FR 53654).

a. Updated References to QualityNet System Administrator and to No Longer Require Active Account To Qualify for Payment

The previously finalized QualityNet security administrator requirements, including those for setting up a QualityNet account and the associated timelines, are described in the FY 2013 IPPS/LTCH final rule (77 FR 53654).

In the FY 2022 IPF PPS proposed rule, we proposed to use the term ''QualityNet security official'' instead of ''QualityNet system administrator'' to denote the exercise of authority invested in the role and align with the Hospital Outpatient Quality Reporting Program and other programs (86 FR 19512). The term ''security official'' would refer to ''the individual(s)'' who have responsibilities for security and account management requirements for a IPF's QualityNet account. To clarify, this update in terminology will not change the individual's responsibilities or add burden.

We invited public comment on our proposal to replace the term ''QualityNet system administrator'' with ''QualityNet security official.''

We did not receive any public comments on this proposal.

We are finalizing our proposal to replace the term ''Quality Net system administrator'' with ''QualityNet security official'' as proposed.

Additionally, we proposed to no longer require IPFs to maintain an active QualityNet security official account to qualify for payment. As we reviewed the requirements for the security official role and the basic user [165] role to identify the most appropriate language to describe the distinguishing authority invested in the security official role, we recognized that the QualityNet security official is not required for submitting data—a basic user can serve in this role—but remains necessary to set up QualityNet basic user accounts and for security purposes. Therefore, consistent with adopting the security official term to differentiate the unique security authority and responsibilities of the role from the data submission responsibilities of the basic user role, we would continue to require a QualityNet basic user account to meet IPFQR Program requirements, including data submission and administrative requirements, while recommending, but not requiring, that hospitals maintain an active QualityNet security official account.

We welcomed public comments on our proposal to no longer require facilities to maintain an active QualityNet security official account to qualify for payment.

We received the following comments in response to our proposal.

Comment: Many commenters supported removal of the requirement to have an active QualityNet Security Official for the complete year to meet IPFQR Program requirements and therefore be eligible to receive a full payment update.

Response: We thank these commenters for their support. We note that IPFs that do not meet all IPFQR Program requirements must receive a 2 percent reduction to their annual payment update.

After review of the public comments received, we are finalizing our proposal to no longer require facilities to maintain an active QualityNet security official account to qualify for payment as proposed.

b. Updated Reference to QualityNet Administrator in Code of Federal Regulations

We proposed to revise our regulation at § 412.434(b)(3) by replacing ''QualityNet system administrator'' with ''QualityNet security official.'' The term ''QualityNet security official'' refers to the individual(s) who have responsibilities for security and account management requirements for a hospital's QualityNet account. To clarify, this update in terminology would not change the individual's responsibilities or add burden. The revised paragraph (b)(3) reads: ''Contact information for the inpatient psychiatric facility's chief executive officer and QualityNet security official, including each individual's name, email address, telephone number, and physical mailing address.''

We invited public comment on our proposal to replace the term ''QualityNet system administrator'' with ''QualityNet security official'' at § 412.434(b)(3).

We did not receive any public comments in response to our proposal.

We are finalizing our proposal to no longer require facilities to replace the term ''QualityNet system administrator'' with ''QualityNet security official'' at § 412.434(b)(3) as proposed.

2. Data Submission Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50899 through 50900), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38472 through 38473) for our previously finalized data submission requirements. In this final rule, we are finalizing our proposal to adopt one measure for the FY 2023 payment determination and subsequent years and one measure for the FY 2024 payment determination and subsequent years. Data submission requirements for each of these measures are described in the following subsections. Additionally, we are finalizing our proposal to adopt patient level data submission for certain chart abstracted measures beginning with data submitted for the FY 2023 payment determination and subsequent years; details of this proposal are in subsection c. of this section.

a. Data Submission Requirements for FY 2023 Payment Determination and Subsequent Years

The measure we are finalizing for FY 2023 payment determination and subsequent years (the COVID–19 Vaccination Coverage Among HCP measure) requires facilities to report data on the number of HCP who have received completed vaccination course of a COVID–19 vaccine through the CDC's National Healthcare Safety Network (NHSN). Specific details on data submission for this measure can be found in the CDC's Overview of the Healthcare Safety Component, available at *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf.* For each CMS Certification Number (CCN), a percentage of the HCP who received a completed vaccine course of the COVID–19 vaccination would be calculated and publicly reported, so that the public would know what percentage of the HCP have been vaccinated in each IPF.

For the COVID–19 HCP Vaccination measure, we proposed that facilities would report the numerator and denominator for the COVID–19 HCP vaccination measure to the NHSN for at least one week each month, beginning in October 2021 for the October 1, 2021 through December 31, 2021 reporting period affecting the FY 2023 payment determination. If facilities report more than one week of data in a month, the most recent week's data would be used to calculate the measure. Each quarter, the CDC would calculate a single quarterly result of COVID–19 vaccination coverage which would summarize the data submitted by IPFs for each of the three weeks of data submitted over the three-month period. CMS will publicly report the CDC's quarterly summary of COVID–19 vaccination coverage for IPFs.

We invited public comment on our proposal to require facilities to report the COVID–19 HCP vaccination measure.

We did not receive any comments in response to our proposal.

We are finalizing our proposal to require facilities to report the COVID–19 HCP vaccination measure as proposed.

b. Data Submission Requirements for FY 2024 Payment Determination and Subsequent Years

Because the Follow-Up After Psychiatric Hospitalization (FAPH) measure would be calculated by CMS using Medicare Fee-for-Service claims, there will be no additional data submission requirements for the FY 2024 payment determination and subsequent years. Therefore, we did not propose any changes to our data submission policies associated with the proposal to adopt this measure.

[165] We also noted that a basic user is a QualityNet user who (1) does not have the registration access described for security officials, (2) has the appropriate data entry roles and permissions for program participation, (3) can submit and review measures and non-measure data, (4) signs and submits the Data Accuracy Completeness Acknowledgement (DACA) form, and (5) refreshes their QualityNet account password every 180 days to ensure that the facility's IPFQR Program Notice of Participation status is ''Participating.''

c. Patient-Level Reporting for Certain Chart-Abstracted Measures Beginning With FY 2024 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657), we finalized that IPFs participating in the IPFQR Program must submit data to the Web-Based Measures Tool found in the Inpatient Psychiatric Facility section of the QualityNet website's secure portal between July 1 and August 15 of each year. We noted that the data input forms within the Quality Net secure portal require submission of aggregate data for each separate quarter. In the FY 2014 IPPS/LTCH PPS final rule, we clarified our intent to require that IPFs submit aggregate data on measures on an annual basis via the Web-Based Measures Tool found in the IPF section of the Quality Net website's secure portal and that the forms available require aggregate data for each separate quarter (78 FR 50899 through 50900). In the FY 2016 IPF PPS final rule (80 FR 46716), we updated our data submission requirements to require facilities to report data for chart-abstracted measures to the Web-Based Measures Tool on an aggregate basis by year, rather than by quarter. Additionally, we discontinued the requirement for reporting by age group. We updated these policies in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38472 through 38473) to change the specification of the submission deadline from exact dates to a 45-day submission period beginning at least 30 days following the end of the data collection period.

In the FY 2019 IPF PPS final rule (83 FR 38607), we observed that reporting aggregate measure data increases the possibility of human error, such as making typographical errors while entering data, which cannot be detected by CMS or by data submission systems. We noted that unlike patient-level data reporting, aggregate measure data reporting does not allow for data accuracy validation, thereby lowering the ability to detect error. We stated that we were considering requiring patient-level data reporting (data regarding each patient included in a measure and whether the patient was included in each numerator and denominator of the measure) of IPFQR measure data in the future. We sought public comment on including patient-level data collection in the IPFQR program. Several commenters expressed support for patient-level data collection, observing that it provides greater confidence in the data's validity and reliability. Other commenters recommended that CMS use a system that has already been tested and used for IPF data reporting or work with IPFs in selecting a system so that any selected system would avoid additional burden.

We believe that patient-level data reporting would improve the accuracy of the submitted and publicly reported data without increasing burden. As we considered the current IPFQR measure set, we determined that patient-level reporting of the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) measure and Hours of Seclusion Use (HBIPS–3,[166] NQF #0641) measure would be appropriate for the numerators of these measures only, because these measures are calculated with a denominator of 1,000 hours rather than a denominator of patients who meet specific criteria for inclusion in the measure. Therefore, we proposed to require reporting patient-level information for the numerators of these measures only. For the remainder of the chart-abstracted measures in the IPFQR Program we proposed to require patient-level reporting of the both the numerator and the denominator. Table 7 lists the proposed FY 2023 IPFQR measure set categorized by whether we would require patient-level data submission through the QualityNet secure portal.

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[166] We note that in the FY 2022 IPF PPS proposed rule this incorrectly read HBIPS–2 (86 FR 19514). We have corrected it to HBIPS–3 here.

TABLE 7: Patient-level data submission requirements for FY 2024 IPFQR Program measure set

NQF #	Measure ID	Measure	Patient-Level Data Submission
0640	HBIPS-2	Hours of Physical Restraint Use	Yes, numerator only
0641	HBIPS-3	Hours of Seclusion Use	Yes, numerator only
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification	Yes
0576	FUH	Follow-Up After Hospitalization for Mental Illness	No (claims-based)
N/A*	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention	Yes
N/A*	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge	Yes
N/A*	TOB-2 and TOB-2a	Tobacco Use Treatment Provided or Offered and TOB-2a Tobacco Use Treatment	Yes
N/A*	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge	Yes
1659	IMM-2	Influenza Immunization	Yes
N/A*	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	Yes
N/A*	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or any Other Site of Care)	Yes
N/A	N/A	Screening for Metabolic Disorders	Yes
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility	No (claims-based)
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric Discharge	No (claims-based)
TBD	COVID HCP	COVID-19 Healthcare Personnel (HCP) Vaccination Measure	No (calculated for HCP)

* Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

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Submission of aggregate data requires facilities to abstract patient-level data, then calculate measure performance prior to submitting data through the QualityNet website's secure portal. For measures for which we would require patient-level data submission, we would allow facilities to submit data using a tool such as the CMS Abstraction & Reporting Tool (CART). This is the tool we use in our other quality reporting and value-based purchasing programs, and therefore, we believe that many facilities may already have familiarity with using this tool to abstract and report data. Additionally, the tool has been specifically designed to facilitate data reporting and minimize provider burden.

We note that under aggregate data reporting, facilities submit aggregate numerators and aggregate denominators for all measures to CMS in the Hospital Quality Reporting (HQR) system. These aggregate numerators and denominators are generally calculated by manually abstracting the medical record of each included patient using the algorithm, a paper tool, or a vendor abstraction tool. After each required medical record has been abstracted, the numerator and denominator results are added up and submitted as aggregate values in the HQR system. Under our patient level data reporting proposal, facilities would still manually abstract the medical record using either a vendor abstraction tool or an abstraction tool provided by CMS. The vendor abstraction tool or the CMS tool would then produce an individual XML file for each of the cases abstracted. Instead of submitting the aggregate data, the IPF would log into HQR and upload batches of XML files that contain patient level data for each measure with data from all patients whose records were abstracted, and CMS would calculate the aggregate numerators, aggregate denominators, and measure rates from those XML file submissions. Because facilities must abstract patient-level data as one step in calculating measure results, we do not believe that requiring patient-level data submission would increase provider costs or burden associated with measure submission.

Because we believe that patient-level data would improve the data accuracy without increasing provider burden, we proposed to adopt patient-level data reporting for numerators only for the Hours of Physical Restraint Use (HBIPS–2, NQF #0640) and the Hours of Seclusion Use (HBIPS–3, NQF #0631) for numerators and denominators for the following 9 chart-abstracted IPFQR Program measures as detailed in Table 7: Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (NQF #0560); Alcohol Use Brief Intervention Provided or Offered and SUB–2a Alcohol Use Brief Intervention; Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB–3a Alcohol and Other Drug Use Disorder Treatment at Discharge; Tobacco Use Treatment Provided or Offered and TOB–2a Tobacco Use Treatment; Tobacco Use Treatment Provided or Offered at Discharge and TOB–3a Tobacco Use Treatment at Discharge; Influenza Immunization (NQF #1659); Transition Record with Specified Elements Received by Discharged Patients (discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care); Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or any Other Site of Care); and Screening for Metabolic Disorders.

We believe that it is appropriate to transition to patient-level reporting incrementally. This would allow facilities to become familiar with the data submission systems and to provide feedback on any challenges they face in reporting data to us. Therefore, we proposed to allow voluntary patient-level data submission for the FY 2023 payment determination (that is, data submitted during CY 2022). We note that because participation in patient-level reporting for these chart-abstracted measures would be voluntary for this one-year period, facilities would be able to choose whether to submit measure data in aggregate or at the patient level, and would not face a payment reduction as long as they submit all measure data either at the patient level or in aggregate for each measure for which reporting is required, and as long as they met all other IPFQR Program requirements. Therefore, we are proposed to allow voluntary patient-level reporting prior to requiring such data submission for one year prior to the FY 2024 payment determination. We will ensure that facilities have guidance available through our standard communications channels (that is, listserv announcements, educational webinars, and training material on the QualityNet website).

We also proposed to require patient-level data submission for these chart-abstracted measures for the FY 2024 payment determination (that is, data submitted during CY 2023) and subsequent years.

We welcomed comment on our proposals to allow voluntary patient-level data reporting for these chart-abstracted measures for the FY 2023 payment determination and then to require patient-level data reporting for the FY 2024 payment determination and subsequent years.

We received the following comments in response to our proposal.

Comment: Many commenters supported the adoption of patient-level reporting. Many of these commenters supported initiating the process with one year of voluntary participation. One commenter observed that having patient level data would help accurately identify trends and improve outcomes and with demographic data could help identify health disparities. One commenter specifically supported the numerator only patient-level reporting for HBIPS–2 and HBIPS–3. One commenter observed that HBIPS–2 was listed twice in the proposed rule (86 FR 19514).

Response: We thank these commenters for their support.

Comment: Some commenters recommended that CMS use a more gradual transition to patient-level reporting. One commenter specifically recommended two cycles of voluntary reporting to ensure that the data submission system works properly. Others recommended that CMS provide additional guidance and education, including XML specifications or other reporting templates prior to the voluntary reporting period. One commenter recommended aligning guidance across programs. One commenter observed that the start date for collecting data for the mandatory reporting period is before the data submission timeframe for the voluntary reporting period.

Response: We recognize that IPFs will need additional guidance and education in preparation for patient-level reporting. We will provide templates, guidance, and education and outreach sessions prior to beginning patient level reporting. We note that, to the extent feasible, we will align guidance across programs. We do not believe that it is necessary to have a longer voluntary reporting period because many IPFs also have experience with these tools already and we have extensive experience with patient-level reporting, both using electronic data reporting systems, and using tools such as the CMS Abstraction & Reporting Tool (CART) in our other quality reporting programs and intend to provide templates, guidance and education and outreach to IPFs.

Comment: Some commenters recommended that CMS not require patient level reporting for measures proposed for removal.

Response: We note that the measure being removed from the IPFQR Program (Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or any Other Site of Care)) is being removed for FY 2024 payment determination and subsequent years. The first year of mandatory patient-level reporting is FY 2024 payment determination. Therefore, this measure will no longer be in the program when patient-level reporting is required. We further note that we are not finalizing our proposals to remove Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention (SUB–2/2a) and Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB–2/2a); and therefore these patient-level data reporting will be required for these measures beginning with the FY 2024 payment determination.

Comment: Some commenters oppose patient level reporting because of a lack of technology. Some commenters observed that CMS should assist with development of EHRs in the same way they did for acute care hospitals. One commenter observed that patient-level reporting would be burdensome without EHR technology.

Response: We disagree with commenters that EHR technology is necessary for patient level reporting and note that acute care hospitals reported patient-level data for the Hospital IQR Program prior to the introduction of the HITECH act and associated meaningful use incentives. We further note that because IPFs must abstract the same data from patient records regardless of whether they are reporting at the patient-level or in aggregate, we do not believe that submitting patient-level data is more burdensome than aggregate data reporting for providers whether or not they have EHR technology.

Comment: One commenter requested clarification on the start date for voluntary patient-level data submission for FY 2023. This commenter specifically requested clarification on whether that would be for discharges beginning for FY 2023 or CY 2023.

Response: The voluntary patient-level data submission period is for FY 2023 payment determination. This applies to the data submitted during CY 2022

(which affects FY 2023 payment determination). Data submitted during CY 2022 covers discharges that occur during CY 2021.

After review of the public comments we received, we are finalizing our proposal to allow voluntary patient-level data reporting for these chart-abstracted measures for the FY 2023 payment determination and then to require patient-level data reporting for the FY 2024 payment determination and subsequent years as proposed.

3. Considerations for Data Validation Pilot

As discussed in section IV.J.4 and in the FY 2019 IPF PPS final rule, we are concerned about the limitations of aggregate data submission (83 FR 28607). One such concern was that the ability to detect error is lower for aggregate measure data reporting than for patient-level data reporting (that is, data regarding each patient included in a measure and whether the patient was included in the numerator and denominator of the measure). In the FY 2022 IPF PPS proposed rule, we noted that if we finalize our proposal to adopt patient-level data requirements, we would be able to adopt a data validation policy for the IPFQR Program in the future (86 FR 19515). We believe that it would be appropriate to develop such a policy incrementally through adoption of a data validation pilot prior to national implementation of data validation within the IPFQR Program. We sought public input on elements of a potential data validation pilot, for example, the number of measures to validate, number of participating facilities, whether the pilot should be mandatory or voluntary, potential thresholds for determining measure accuracy, or any other policies that commenters believe would be appropriate to include in a data validation pilot or eventual data validation policy.

We received the following comments in response to our request.

Comment: Many commenters supported the concept of data validation but recommended that CMS ensure a stable and successful patient-level reporting process prior to developing a data validation plan.

One commenter recommended using two measures and 200 hospitals to pilot data validation.

Some commenters did not support eventual adoption of validation for the IPFQR program because of the belief that data validation would be burdensome. One commenter observed data validation is only necessary in pay-for-performance programs.

Response: We thank these commenters for this input and will take it into consideration if we develop a data validation program for the IPFQR Program.

4. Reporting Requirements for the FY 2022 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53656 through 53657), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50900 through 50901), and the FY 2015 IPF PPS final rule (79 FR 45976 through 45977) for our previously finalized reporting requirements. We did not propose any changes to these policies.

5. Quality Measure Sampling Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), the FY 2016 IPF PPS final rule (80 FR 46717 through 46719), and the FY 2019 IPF PPS final rule (83 FR 38607 through 38608) for discussions of our previously finalized sampling policies. In the FY 2022 IPF PPS proposed rule, we noted that neither the measure we proposed to remove (FUH—NQF #0576) nor the measure we proposed to adopt (FAPH) if we remove the FUH–NQF #0576 are affected by our sampling policies because these are both calculated by CMS using Medicare Fee-for-Service claims and, therefore, apply to all Medicare patients in the denominator (86 FR 19515). Furthermore, the denominator of the COVID–19 Healthcare Personnel Vaccination measure we are adopting in this final rule is all healthcare personnel, and therefore, this measure is not eligible for sampling. We did not propose any changes to these policies.

6. Non-Measure Data Collection

We refer readers to the FY 2015 IPF PPS final rule (79 FR 45973), the FY 2016 IPF PPS final rule (80 FR 46717), and the FY 2019 IPF PPS final rule (83 FR 38608) for our previously finalized non-measure data collection policies. We did not propose any changes to these policies.

7. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658) for our previously finalized DACA requirements. We did not propose any changes to these policies.

K. Reconsideration and Appeals Procedures

We refer readers to 42 CFR 412.434 for the IPFQR Program's reconsideration and appeals procedures. We did not propose any changes to these policies.

L. Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50903), the FY 2015 IPF PPS final rule (79 FR 45978), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38473 through 38474) for our previously finalized ECE policies. We did not propose any changes to these policies.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' (as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations) 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 PRA 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 FY 2022 IPF PPS proposed rule (86 FR 19480) we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). As indicated in section V.2.c.(1) of this final rule, we received some comments that generally discuss the burden of reporting through NHSN, but not comments specific to our information collection estimates. We have not made any changes from what was proposed.

A. Final ICRs for the (IPFQR) Program

The following final requirement and burden changes will be submitted to OMB for approval under control number 0938–1171 (CMS–10432).

1. Wage Estimates

In the FY 2020 IPF PPS final rule (84 FR 38468), which was the most recent rule in which we adopted updates to the IPFQR Program, we estimated that reporting measures for the IPFQR Program could be accomplished by a Medical Records and Health Information Technician (BLS Occupation Code: 29–2071) with a median hourly wage of $18.83/hr (May 2017). In May 2019, the U.S. Bureau of Labor Statistics (BLS) revised their $18.83/hr wage figure to $20.50/hr (May 2019).[167] In response, we proposed to adjust our cost estimates using the updated median wage rate figure of $20.50/hr., an increase of $1.67/hr. We are finalizing our proposal to use the $20.50/hr wage in this FY 2022 final rule.

Under OMB Circular A–76, in calculating direct labor, agencies should not only include salaries and wages, but also ''other entitlements'' such as fringe benefits and overhead.[168] Consistent with our past approach, we continue to calculate the cost of fringe benefits and overhead at 100 percent of the median hourly wage (81 FR 57266). This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and methods of estimating these costs vary widely from study to study. Therefore, using these assumptions, we estimate an hourly labor cost increase from $37.66/hr ($18.83/hr base salary + $18.83/hr fringe benefits and overhead) to $41.00/hr ($20.50/hr base salary + $20.50/hr fringe benefits and overhead). Table 8 presents these assumptions.

TABLE 8: Wage assumptions for the IPFQR Program

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Medical Records and Health Information Technician	29-2071	20.50	20.50	41.00

2. ICRs Regarding the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

In subsection 2.a., we restate our currently approved burden estimates. In subsection 2.b., we estimate the adjustments in burden associated with the updated BLS wage rate, our facility estimates, and our case estimates. In subsection 2.c., we estimate the changes in burden associated with the finalized policies in this rule. Finally, in subsection 2.d., we provide an overview of the total estimated burden.

a. Currently Approved Burden

For a detailed discussion of the burden for the IPFQR Program requirements that we have previously adopted, we refer readers to the following rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53673);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50964);
- The FY 2015 IPF PPS final rule (79 FR 45978 through 45980);
- The FY 2016 IPF PPS final rule (80 FR 46720 through 46721);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57265 through 57266);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38507 through 38508);
- The FY 2019 IPF PPS final rule (83 FR 38609 through 38612); and
- The FY 2020 IPF PPS final rule (84 FR 38468 through 38476).

Tables 9, 10, and 11 provide an overview of our currently approved burden. These tables use our previous estimate of $37.66/hr ($18.83/hr base salary plus $18.83/hr fringe benefits and overhead) hourly labor cost. For more information on our currently approved burden estimates, please see Supporting Statement A on the Office of Information and Regulatory Affairs (OIRA) website.[169]

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[167] *https://www.bls.gov/oes/current/oes292098.htm* (Accessed on June 28, 2021).

[168] *http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction.*

[169] *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201908-0938-011.*

TABLE 9: Currently Approved Measure Collection and Reporting Burden

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Time per Case (hours)	Annual Time per Facility (hours)	Number IPFs	Total Annual Time (hours)	Total Annual Cost ($)
0640	HBIPS-2	Hours of Physical Restraint Use	1,283	0.25	320.75	1,679	538,539.25	20,281,388
0641	HBIPS-3	Hours of Seclusion Use	1,283	0.25	320.75	1,679	538,539.25	20,281,388
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification	609	0.25	152.25	1,679	255,627.75	9,626,941
N/A	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered	609	0.25	152.25	1,679	255,627.75	9,626,941
N/A	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge	609	0.25	152.25	1,679	255,627.75	9,626,941
0576	FUH	Follow-Up After Hospitalization for Mental Illness*	0	0	0	0	0	0
N/A	TOB-2 and TOB-2a	Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment	609	0.25	152.25	1,679	255,627.75	9,626,941
N/A	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge	609	0.25	152.25	1,679	255,627.75	9,626,941
1659	IMM-2	Influenza Immunization	609	0.25	152.25	1,679	255,627.75	9,626,941
0647	N/A	Transition Record with Specified	609	0.25	152.25	1,679	255,627.75	9,626,941

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Time per Case (hours)	Annual Time per Facility (hours)	Number IPFs	Total Annual Time (hours)	Total Annual Cost ($)
		Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)						
0648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	609	0.25	152.25	1,679	255,627.75	9,626,941
N/A	N/A	Screening for Metabolic Disorders	609	0.25	152.25	1,679	255,627.75	9,626,941
2860	N/A	Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF*	0	0	0	0	0	0
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric Discharge*	0	0	0	0	0	0
TOTAL			8,047	Varies	2,011.75	1,679	3,377,728	127,205,245

* CMS will collect these data using Medicare Part A and Part B claims; therefore, these measures will not require facilities to submit data on any cases.

TABLE 10: Currently Approved Non-Measure Data Collection and Reporting Burden

Tasks	Number IPFs	Annual Time per Facility (hours)	Total Annual Time (hours)	Wage Rate ($/hr)	Cost per IPF ($)	Total Annual Cost for All IPFs ($)
Non-measure Data Collection and Submission	1,679	2.0	3,358	37.66	75.32	126,462

TABLE 11: Currently Approved Total Burden

Requirement	Respondents	Responses	Time (hours)	Cost ($)
Measure Data Collection and Reporting	1,679	13,510,913 (8,047 responses or cases per facility * 1,679 facilities)	3,377,728	127,205,245
Non-Measure Data Collection and Reporting	1,679	6,716 (4 * responses per facility * 1,679 facilities)	3,358	126,462
Notice of Participation, Data Accuracy Acknowledgment, and Vendor Authorization Form*	N/A	N/A	N/A	N/A
TOTAL	1,679	13,517,629	3,381,086	127,331,707

* The 15 minutes per measure for chart abstraction under Measure Data Collection and Reporting also includes the time for completing and submitting any forms.

b. Final Adjustments in Burden due to Updated Wage, Facility Count, and Case Count Estimates

In the FY 2020 IPF PPS final rule (84 FR 38468), which is the most recent rule, that updated the IPFQR Program policies, we estimated that there were 1,679 participating IPFs and that (for measures that require reporting on the entire patient population) these facilities will report on an average of 1,283 cases per facility. In this FY 2022 rule, we are finalizing our proposal to update our facility count and case estimates by using the most recent data available. Specifically, we estimate that there are now approximately 1,634 facilities (a decrease of 45 facilities) and an average of 1,346 cases per facility (an increase of 63 cases per facility). Tables 12, 13, and 14, depict the effects of these updates, as well as the wage rate update to $41.00/hr described in section V.A.1 of the preamble of this final rule, on our previously estimated burden.

TABLE 12: Measure Collection and Reporting Burden Based on Updated Wage Rate, Facility Count, and Case Count

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Time per Case (hours)	Annual Time per Facility (hours)	Number IPFs	Total Annual Time (hours)	Total Annual Cost ($)
0640	HBIPS-2	Hours of Physical Restraint Use	1,346	0.25	336.50	1,634	549,841	22,543,481
0641	HBIPS-3	Hours of Seclusion Use	1,346	0.25	336.50	1,634	549,841	22,543,481
0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification	609*	0.25	152.25	1,634	248,776.5	10,199,836.50
N/A	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention Provided	609*	0.25	152.25	1,634	248,776.5	10,199,836.50
N/A	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge	609*	0.25	152.25	1,634	248,776.5	10,199,836.50
0576	FUH	Follow-Up After Hospitalization for Mental Illness*	0	0	0	0	0	0
N/A	TOB-2 and TOB-2a	Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment	609*	0.25	152.25	1,634	248,776.5	10,199,836.50
N/A	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge	609*	0.25	152.25	1,634	248,776.5	10,199,836.50
1659	IMM-2	Influenza Immunization	609*	0.25	152.25	1,634	248,776.5	10,199,836.50
0647	N/A	Transition Record with	609*	0.25	152.25	1,634	248,776.5	10,199,836.50

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Time per Case (hours)	Annual Time per Facility (hours)	Number IPFs	Total Annual Time (hours)	Total Annual Cost ($)
		Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)						
0648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	609*	0.25	152.25	1,634	248,776.5	10,199,836.50
N/A	N/A	Screening for Metabolic Disorders	609*	0.25	152.25	1,634	248,776.5	10,199,836.50
2860	N/A	Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF*	0	0	0	0	0	0
3205	Med Cont	Medication Continuation Following Inpatient Psychiatric Discharge*	0	0	0	0	0	0
N/A	COVID-19 HCP	COVID-19 Vaccination Rate Among Healthcare Personnel	0**	0	0	0	0	0
N/A	FAPH	Follow-Up After Psychiatric Hospitalization	0	0	0	0	0	0
TOTAL			8,173	Varies	2,043.25	1,634	3,338,671	136,885,491

* Under our previously finalized ''global sample'' (80 FR 46717 through 46718) we allow facilities to apply the same sampling methodology to all measures eligible for sampling. In the FY 2016 IPF PPS final rule (80 FR 46718), we finalized that facilities with between 609 and 3,056 cases that choose to participate in the global sample would be required to report data for 609 cases. Because facilities are only required to submit data on a number specified by the global sampling methodology, rather than abstracting data for all patients or applying measure specific sampling methodologies, we believe that the number of cases under the global sample is a good approximation of IPF burden associated with these measures. Therefore, for the average IPF discharge rate of 1,346 discharges versus the previously estimated 1,283, the global sample continues to require abstraction of 609 records.
** The COVID-19 HCP measure will be calculated using data submitted to the CDC under a separate OMB Control Number (0920-1317).

TABLE 13: Non-Measure Data Collection and Reporting Burden Based on Updated Wage Rate, Facility Count, and Case Count

Tasks	Number IPFs	Annual Time per Facility (hours)	Total Annual Time (hours)	Wage Rate ($/hr)	Cost per IPF ($)	Total Annual Cost for All IPFs ($)
Non-measure Data Collection and Submission	1,634	2.0	3,268	41.00	82.00	133,988

TABLE 14: Total Burden Based on Updated Wage Rate, Facility Count, and Case Count

Requirement	Respondents	Responses	Time (hours)	Cost ($)
Measure Data Collection and Reporting (See Table 12)	1,634	13,354,682 (8,173 responses per facility * 1,634 facilities)	3,338,671	136,885,491
Non-Measure Data Collection and Reporting (See Table 13)	1,634	6,536 (4 responses per facility * 1,634 facilities)	3,268	133,988
TOTAL	1,634	13,361,218	3,341,939	137,019,479

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c. Changes in Burden due to This Final Rule

(1) Updates Due to Final Measure Adoptions

In section IV.E of this preamble, we are adopting the following two measures:

- COVID–19 Vaccination Among HCP for FY 2023 Payment Determination and Subsequent Years; and
- Follow-Up After Psychiatric Hospitalization (FAPH) for FY 2024 Payment Determination and Subsequent Years.

We are adopting the COVID–19 Vaccination among HCP measure beginning with an initial reporting period from October 1 to December 31, 2021 affecting the FY 2023 payment determination followed by quarterly reporting beginning with the FY 2024 payment determination and subsequent years. IPFs will submit data through the CDC's NHSN. The NHSN is a secure, internet-based system that is maintained by the CDC and provided free. The CDC does not estimate burden for COVID–19 vaccination reporting since the department has been granted a waiver under Section 321 of the National Childhood Vaccine Injury Act of 1986 (NCVIA).[170]

Although the burden associated with the COVID–19 HCP Vaccination measure is not accounted for due to the NCVIA waiver, the burden is set forth here and will be accounted for by the CDC under OMB control number 0920–1317.

Consistent with the CDC's experience of collecting data using the NHSN, we estimate that it will take each IPF on average approximately 1 hour per month to collect data for the COVID–19 Vaccination Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. This burden is comprised of administrative time and wages. We believe it would take an Administrative Assistant[171] between 45 minutes (0.75 hr) and 1 hour and 15 minutes (1.25 hr) to enter the data into NHSN. For the CY 2021 reporting period (consisting of October 1, 2021 through December 31, 2021) 3 months are required. For the CY 2021 reporting period/FY 2023 payment determination, IPFs would incur an additional burden between 2.25 hours (0.75 hours * 3 responses at 1 response per month) and 3.75 hours (1.25 hours * 3 responses at 1 response per month) per IPF. For all 1,634 IPFs, the total time would range from 3,676.5 hours (2.25 hours * 1,634 IPFs) and 6,127.5 hours (3.75 hours * 1,634 IPFs).

Each IPF would incur an estimated cost of between $27.47 (0.75 hour * $36.62/hr) and $45.78 (1.25 hours * $36.62/hr) monthly and between $82.40 (2.25 hours * $36.62/hr) and $137.33 (3.75 hours * $36.62/hr) in total over the CY 2021 reporting period to complete this task. Thereafter, 12 months of data are required annually. Therefore, IPFs would incur an additional annual burden between 9 hours (0.75 hours/month * 12 months) and 15 hours (1.25 hours/month * 12 months) per IPF and between 14,706 hours (9 hours/IPF * 1,634 IPFs) and 24,510 hours (15 hours/IPF * 1,634 IPFs) for all IPFs. Each IPF would incur an estimated cost of between $329.58 (9 hours × $36.62/hr) and $549.30 annually (15 hours × $36.62/hr). The estimated cost across all 1,634 IPFs would be between $134,641.60 ($82.40/IPF * 1,634 IPFs) and $224,397.22 ($137.33/IPF * 1,634 IPFs) for the CY 2021 reporting period. The estimated cost across all 1,634 IPFs would be between $538,533.72 ($329.58/IPF * 1,634 IPFs) and $897,556.20 ($549.30/IPF * 1,634 IPFs) annually thereafter. Since the burden falls under the authority of the CDC, we have not added such burden to Table 16.

We recognize that many healthcare facilities are also reporting other COVID–19 data to HHS. We believe the benefits of requiring IPFs to report data on the COVID–19 HCP Vaccination measure to assess whether they are taking steps to limit the spread of

[170] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[171] *https://www.bls.gov/oes/current/oes436013.htm* (accessed on March 30, 2021). The hourly rate of $36.62 includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

COVID–19 among their healthcare workers and to help sustain the ability of IPFs to continue serving their communities throughout the PHE and beyond outweigh the costs of reporting. In our proposed rule, we welcomed comments on the time to collect data and enter it into the NHSN. While we did receive some comments addressing the burden of NHSN reporting, which we address in section IV.E.2 of this rule, we did not receive any public comments on the estimated time to collect and submit such data.

We further note that as described in section IV.E.3 of this preamble, we will calculate the FAPH measure using Medicare Part A and Part B claims that IPFs and other providers (specifically outpatient providers who provide the follow-up care) submit for payment. Since this is a claims-based measure, there is no additional burden outside of submitting the claim. The claim submission is approved by OMB under control number 0938–0050 (CMS–2552–10). This rule does not warrant any changes under that control number.

(2) Updates Due to Final Measure Removals

In section IV.F. of this preamble, we are finalizing our proposals to remove the following two measures for the FY 2024 payment determination and subsequent years:

- Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care); and
- FUH—Follow-Up After Hospitalization for Mental Illness (NQF #0576).

We note that we are not finalizing our proposals to remove the following two measures:

- SUB–2—Alcohol Use Brief Intervention Provided or Offered and the subset measure SUB–2a Alcohol Use Brief Intervention Provided; and
- TOB–2—Tobacco Use Treatment Provided or Offered and the subset measure TOB–2a Tobacco Use Treatment.

For the FY 2024 payment determination, data on CY 2022 performance would be reported during the summer of 2023. Therefore, we are applying the burden reduction that would occur to the FY 2023 burden calculation. One of the measures we are removing (the Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) measure) falls under our previously finalized ''global sample'' (80 FR 46717 through 46718) and, therefore, would require abstraction of 609 records. We estimate that removing this measure would result in a decrease in burden of 152.25 hours per facility (609 cases per facility * 0.25 hours per case), or 248,776.5 hours (152.25 hours/facility × 1,634 facilities) across all IPFs. Therefore, the decrease in costs for each measure is approximately $6,242.25 per IPF ($41.00/hr * 152.25 hours), or $10,199,836.50 across all IPFs ($6,242.25/facility * 1,634 facilities).

We have previously estimated that the FUH (NQF #0576) measure does not have any reporting burden because it is calculated from Medicare FFS claims. Therefore, we do not anticipate a reduction in facility burden associated with the removal of this measure. Table 15 describes our estimated reduction in burden associated with removing these two measures.

TABLE 15: Burden Updates Due to Final Measure Removals

NQF #	Measure ID	Measure Description	Estimated Cases (per facility)	Time per Case (hours)	Annual Time per Facility (hours)	Number IPFs**	Total Annual Time (hours)	Total Annual Cost ($)
0576	FUH	Follow-Up After Hospitalization for Mental Illness*	0	0	0	1,634	0	0
0648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	(609)	0.25	152.25	1,634	(248,776.5)	(10,199,836.5050)
TOTAL			(609)	Varies	152.25	1,634	(248,776.5)	(10,199,836.5050)

* CMS will collect these data using Medicare Part A and Part B claims; therefore, these measures will not require facilities to submit data on any cases.

** We note that the previously approved number of IPFs is 1,679; however we adjusted that in Table 12 based on updated data.

***At $41.00/hr

(3) Updates Due to Final Administrative Policies

(a) Updates Associated With Final Updated Reference to QualityNet System Administrator

In section IV.J.1.a of this preamble, we are finalizing our proposal to use the term ''QualityNet security official'' instead of ''QualityNet system administrator.'' Because this final update will not change the individual's responsibilities, we do not believe there would be any changes to the information collection burden as a result of this update. We also do not believe that removing the requirement for facilities to have an active QualityNet security official account to qualify for payment updates will affect burden because we continue to recommend that facilities maintain an active QualityNet security official account.

(b) Updates Associated With Adoption of Patient-Level Reporting for Certain Chart Abstracted Measures

In section IV.J.2.c of this preamble, we are adopting patient-level data submission for the 11 chart-abstracted measures currently in the IPFQR Program measure set (for more details on these measures we refer readers to Table 7). Because submission of aggregate data requires facilities to abstract patient-level data, then calculate measure performance prior to submitting data through the QualityNet website's secure portal, facilities must already abstract patient-level data. Therefore, we do not believe that submitting data that facilities must already calculate through a tool that facilities already have experience using will change provider burden.

d. Overall Burden Summary

Table 16 summarizes the estimated burden associated with the IPFQR Program.

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TABLE 16: Total Estimated IPFQR Program Measure Set Burden Estimates

Measure/ Response Description	Estimated Responses per Facility	Time per Response (hours)	Annual Time per Facility (hours)	Total Annual Responses (Responses per Facility * 1,634 facilities)	Total Annual Time (hours)	Total Annual Cost ($)
Hours of Physical Restraint Use (See Table 12)	1,346	0.25	336.50	2,199,364	549,841	22,543,481
Hours of Seclusion Use (See Table 12)	1,346	0.25	336.50	2,199,364	549,841	22,543,481
Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Alcohol Use Brief Intervention Provided or Offered (SUB-2 and SUB-2a) (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge (SUB-3 and SUB-3a) (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment (TOB-2 and TOB-2a) (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Tobacco Use Treatment Provided or Offered at Discharge and Tobacco Use Treatment at Discharge (TOB-3 and TOB-3a) (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Influenza Immunization (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Screening for Metabolic Disorders (See Table 12)	609*	0.25	152.25	995,106	248,776.5	10,199,836.50
Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF (See Table 12)	0**	0	0	0	0	0
Medication Continuation Following Inpatient Psychiatric Discharge (See Table 12)	0**	0	0	0	0	0
COVID-19 Vaccination Rate Among Healthcare Personnel (See Table 12)	0***	0	0	0	0	0
Follow-Up After Psychiatric Hospitalization (See Table 12)	0**	0	0	0	0	0
SUBTOTAL	7,564	N/A	1,891	12,359,576	3,089,894	126,685,654
Non-Measure Data Collection and Reporting (See Table 13)	4	0.5	2.0	6,536	3,268	133,988
TOTAL	7,568	N/A	1,893	12,366,112	3,093,162	126,819,642

* Under our previously finalized ''global sample'' (80 FR 46717 through 46718) we allow facilities to apply the same sampling methodology to all measures eligible for sampling. In the FY 2016 IPF PPS final rule (80 FR 46718), we finalized that facilities with between 609 and 3,056 cases that choose to participate in the global sample would be required to report data for 609 cases. Because facilities are only required to submit data on a number specified by the global sampling methodology, rather than abstracting data for all patients or applying measure specific sampling methodologies, we believe that the number of cases under the global sample is a good approximation of facility burden associated with these measures. Therefore, for the average IPF discharge rate of 1,346 discharges versus the previously estimated 1,283, the global sample continues to require abstraction of 609 records.

** CMS will collect these data using Medicare Part A and Part B claims; therefore, these measures will not require facilities to submit data on any cases.

*** The COVID-19 HCP measure will be calculated using data submitted to the CDC under a separate OMB Control Number (0920-1317).

The total change in burden associated with this final rule (including all updates to wage rate, case counts, facility numbers, and the measures and administrative policies) is a reduction of 287,924 hours and $512,065 from our currently approved burden of 3,381,086 hours and $127,331,707. We refer readers to Table 17 for details.

TABLE 17: Summary of Final Requirements and Annual Burden Estimates Under OMB Control Number 0938-1171 (CMS-10432)

Program Changes	No. Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
Active Burden	1,679	13,517,629	**Varies**	3,381,086	37.66	127,331,707
Total Burden Under CMS-1750-F (See Table 16)	1,634	12,366,112	**Varies**	3,093,162	41.00	126,819,642
DIFFERENCE	**(45)**	**(1,151,517)**	**Varies**	**(287,924)**	**Varies**	**(512,065)**

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VI. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes updates to the prospective payment rates for Medicare inpatient hospital services provided by IPFs for discharges occurring during FY 2022 (October 1, 2021 through September 30, 2022). We are finalizing our proposal to apply the 2016-based IPF market basket increase of 2.7 percent, less the productivity adjustment of 0.7 percentage point as required by 1886(s)(2)(A)(i) of the Act for a final total FY 2022 payment rate update of 2.0 percent. In this final rule, we are finalizing our proposal to update the IPF labor-related share and update the IPF wage index to reflect the FY 2022 hospital inpatient wage index.

B. Overall Impact

We have examined the impacts of this final rule 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 (the Act), section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). 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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s or with economically significant effects ($100 million or more in any 1 year).

We estimate that the total impact of these changes for FY 2022 payments compared to FY 2021 payments will be a net increase of approximately $80 million. This reflects an $75 million increase from the update to the payment rates (+$100 million from the 2nd quarter 2021 IGI forecast of the 2016-based IPF market basket of 2.7 percent, and -$25 million for the productivity adjustment of 0.7 percentage point), as well as a $5 million increase as a result of the update to the outlier threshold amount. Outlier payments are estimated to change from 1.9 percent in FY 2021 to 2.0 percent of total estimated IPF payments in FY 2022.

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is ''economically significant,'' and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act).

C. Detailed Economic Analysis

In this section, we discuss the historical background of the IPF PPS and the impact of this final rule on the Federal Medicare budget and on IPFs.

1. Budgetary Impact

As discussed in the November 2004 and RY 2007 IPF PPS final rules, we applied a budget neutrality factor to the Federal per diem base rate and ECT payment per treatment to ensure that total estimated payments under the IPF PPS in the implementation period would equal the amount that would have been paid if the IPF PPS had not been implemented. The budget neutrality factor includes the following components: Outlier adjustment, stop-loss adjustment, and the behavioral offset. As discussed in the RY 2009 IPF PPS notice (73 FR 25711), the stop-loss adjustment is no longer applicable under the IPF PPS.

As discussed in section III.D.1 of this final rule, we are updating the wage index and labor-related share in a budget neutral manner by applying a wage index budget neutrality factor to the Federal per diem base rate and ECT payment per treatment. Therefore, the budgetary impact to the Medicare program of this final rule will be due to the market basket update for FY 2022 of 2.7 percent (see section III.A.4 of this final rule) less the productivity adjustment of 0.7 percentage point required by section 1886(s)(2)(A)(i) of the Act and the update to the outlier fixed dollar loss threshold amount.

We estimate that the FY 2022 impact will be a net increase of $80 million in payments to IPF providers. This reflects an estimated $75 million increase from the update to the payment rates and a $5 million increase due to the update to the outlier threshold amount to set total

estimated outlier payments at 2.0 percent of total estimated payments in FY 2022. This estimate does not include the implementation of the required 2.0 percentage point reduction of the market basket update factor for any IPF that fails to meet the IPF quality reporting requirements (as discussed in section V.A. of this final rule).

2. Impact on Providers

To show the impact on providers of the changes to the IPF PPS discussed in this final rule, we compare estimated payments under the IPF PPS rates and factors for FY 2022 versus those under FY 2021. We determined the percent change in the estimated FY 2022 IPF PPS payments compared to the estimated FY 2021 IPF PPS payments for each category of IPFs. In addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the update to the outlier fixed dollar loss threshold amount; the updated wage index data including the updated labor-related share; and the market basket update for FY 2022, as reduced by the productivity adjustment according to section 1886(s)(2)(A)(i) of the Act.

Our longstanding methodology uses the best available data as the basis for our estimates of payments. Typically, this is the most recent update of the latest available fiscal year of IPF PPS claims, and for this final rulemaking, that would be the FY 2020 claims. However, as discussed in section III.F.2 of this final rule, the U.S. healthcare system undertook an unprecedented response to the COVID–19 PHE during FY 2020. Therefore, we considered whether the most recent available year of claims, FY 2020, or the prior year, FY 2019, would be the best for estimating IPF PPS payments in FY 2021 and FY 2022.

As discussed in the FY 2022 IPF PPS proposed rule (86 FR 19524 through 19526), we examined the differences between the FY 2019 and FY 2020 claims distributions to better understand the disparity in the estimate of outlier payments as a percentage of total PPS payments between the two years, which was driving the divergent results in our proposed rule impacts between FY 2019 claims and FY 2020 claims. Based on our analysis, we stated that we believe it is likely that the response to the COVID–19 PHE in FY 2020 has contributed to increases in estimated outlier payments and to decreases in estimated total PPS payments in the FY 2020 claims. Therefore, we proposed, in contrast to our usual methodology, to use the FY 2019 claims to calculate the outlier fixed dollar loss threshold and wage index budget neutrality factor.

We requested comments from stakeholders about likely explanations for the declines in total PPS payments, covered IPF days, and covered IPF stays in FY 2020. Additionally, we requested comments from stakeholders about likely explanations for the observed fluctuations and overall increases in covered lab charges per claim and per day, which we identified through our analysis. Lastly, we requested comments regarding likely explanations for the increases in estimated cost per stay relative to estimated IPF Federal per diem payment amounts per stay.

Comment: We received 1 comment regarding our analysis of FY 2020 claims and 3 comments in support of our proposal to use FY 2019 claims for calculating the outlier fixed dollar loss threshold and wage index budget neutrality factor for FY 2022. One commenter appreciated CMS' recognition of the impact of the COVID–19 PHE on providers. Another commenter agreed with our analysis about the effect of the COVID–19 PHE on the FY 2020 claims, stating their belief that FY 2020 cases were heavily impacted by the intensity of the COVID–19 pandemic, which continues to subside.

Response: We appreciate the support from these commenters. As we discuss later in this section of this final rule, based on the results of our final impact analysis, we continue to believe that the FY 2019 claims are the best available data for estimating payments in this FY 2022 final rulemaking, due to the likely impact of the COVID–19 PHE on IPF utilization in FY 2020. We will continue to analyze data in order to understand its short-term and long-term effects on IPF utilization.

Final Decision: In light of the comments received and after analyzing more recently updated FY 2020 claims, we are finalizing our proposal to use the FY 2019 claims to calculate the outlier fixed dollar loss threshold and wage index budget neutrality factor.

To illustrate the impacts of the FY 2022 changes in this final rule, our analysis presents a side-by-side comparison of payments estimated using FY 2019 claims versus payments estimated using FY 2020 claims. We begin with FY 2019 IPF PPS claims (based on the 2019 MedPAR claims, June 2020 update) and FY 2020 IPF PPS claims (based on the 2020 MedPAR claims, March 2021 update). We estimate FY 2021 IPF PPS payments using these 2019 and 2020 claims, the finalized FY 2021 IPF PPS Federal per diem base rates, and the finalized FY 2021 IPF PPS patient and facility level adjustment factors (as published in the FY 2021 IPF PPS final rule (85 FR 47042 through 47070)). We then estimate the FY 2021 outlier payments based on these simulated FY 2021 IPF PPS payments using the same methodology as finalized in the FY 2021 IPF PPS final rule (85 FR 47061 through 47062) where total outlier payments are maintained at 2 percent of total estimated FY 2021 IPF PPS payments.

Each of the following changes is added incrementally to this baseline model in order for us to isolate the effects of each change:

- The final update to the outlier fixed dollar loss threshold amount.
- The final FY 2022 IPF wage index, the final FY 2022 labor-related share, and the final updated COLA factors.
- The final market basket update for FY 2022 of 2.7 percent less the productivity adjustment of 0.7 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act for a payment rate update of 2.0 percent.

Our final column comparison in Table 18 illustrates the percent change in payments from FY 2021 (that is, October 1, 2020, to September 30, 2021) to FY 2022 (that is, October 1, 2021, to September 30, 2022) including all the payment policy changes in this final rule. For each column, Table 18 presents a side-by-side comparison of the results using FY 2019 and FY 2020 IPF PPS claims.

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TABLE 18: FY 2022 IPF PPS Final Payment Impacts

[Percent Change in columns 3 through 5]

Facility by Type	Number of Facilities		Outlier		FY 2022 Wage Index, LRS, and COLA		Total Percent Change[1]	
	FY 2019 Claims	FY 2020 Claims	FY 2019 Claims	FY 2020 Claims	FY 2019 Claims	FY 2020 Claims	FY 2019 Claims	FY 2020 Claims
(1)	(2)		(3)		(4)		(5)	
All Facilities	1,519	1,534	0.1	-1.1	0.0	0.0	2.1	0.9
Total Urban	1,220	1,235	0.1	-1.1	0.0	0.0	2.1	0.8
Urban unit	739	737	0.2	-1.8	-0.1	-0.1	2.2	0.1
Urban hospital	481	498	0.0	-0.3	0.0	0.0	2.1	1.7
Total Rural	299	299	0.1	-0.7	0.2	0.2	2.2	1.5
Rural unit	239	238	0.1	-0.8	0.1	0.1	2.2	1.3
Rural hospital	60	61	0.1	-0.4	0.4	0.4	2.4	2.0
By Type of Ownership:								
Freestanding IPFs								
Urban Psychiatric Hospitals								
Government	116	123	0.2	-1.7	-0.2	-0.2	2.0	0.1
Non-Profit	95	97	0.1	-0.5	-0.2	-0.1	1.9	1.4
For-Profit	270	278	0.0	-0.1	0.1	0.1	2.1	2.0
Rural Psychiatric Hospitals								
Government	31	32	0.1	-0.8	0.5	0.6	2.6	1.8
Non-Profit	12	12	0.2	-1.2	-0.1	0.0	2.1	0.7
For-Profit	17	17	0.0	0.0	0.4	0.4	2.4	2.4
IPF Units								
Urban								
Government	108	107	0.3	-3.4	0.1	0.1	2.5	-1.4
Non-Profit	479	478	0.2	-1.7	-0.1	-0.1	2.1	0.2
For-Profit	152	152	0.1	-0.7	-0.1	-0.1	2.0	1.2
Rural								
Government	58	57	0.1	-0.4	0.4	0.3	2.4	1.9
Non-Profit	132	131	0.1	-1.0	0.1	0.1	2.2	1.0
For-Profit	49	50	0.1	-0.6	-0.2	-0.2	1.9	1.2
By Teaching Status:								
Non-teaching	1,321	1,336	0.1	-0.8	0.0	0.0	2.1	1.1
Less than 10% interns and residents to beds	109	109	0.2	-1.9	0.1	0.1	2.3	0.2
10% to 30% interns and residents to beds	67	67	0.3	-2.4	-0.1	-0.1	2.2	-0.5
More than 30% interns and residents to beds	22	22	0.4	-3.2	-0.2	-0.1	2.2	-1.3
By Region:								

New England	106	106	0.2	-1.2	-0.4	-0.4	1.8	0.3
Mid-Atlantic	214	216	0.2	-2.0	-0.2	-0.2	2.0	-0.2
South Atlantic	240	243	0.1	-0.7	0.6	0.6	2.7	1.9
East North Central	243	244	0.1	-0.7	-0.2	-0.2	1.9	1.0
East South Central	152	155	0.1	-0.7	-0.5	-0.5	1.6	0.7
West North Central	108	109	0.2	-1.4	0.1	0.1	2.3	0.7
West South Central	224	227	0.1	-0.5	-0.2	-0.3	1.8	1.3
Mountain	103	103	0.1	-0.7	0.3	0.3	2.4	1.6
Pacific	129	131	0.2	-1.4	0.4	0.4	2.6	1.0
By Bed Size:								
Psychiatric Hospitals								
Beds: 0-24	83	88	0.1	-0.5	0.1	0.0	2.1	1.5
Beds: 25-49	79	83	0.1	-0.2	-0.3	-0.3	1.8	1.5
Beds: 50-75	84	88	0.0	-0.1	0.1	0.2	2.1	2.2
Beds: 76 +	295	300	0.1	-0.4	0.1	0.1	2.2	1.7
Psychiatric Units								
Beds: 0-24	536	531	0.2	-1.2	0.0	0.0	2.2	0.7
Beds: 25-49	258	259	0.2	-1.3	0.0	0.0	2.2	0.7
Beds: 50-75	114	114	0.2	-2.0	-0.3	-0.3	2.0	-0.3
Beds: 76 +	70	71	0.3	-2.5	0.0	0.0	2.3	-0.5

[1] This column includes the impact of the updates in columns (3) and (4) in Table 18 above, and of the final IPF market basket increase factor for FY 2022 (2.7 percent), reduced by 0.7 percentage point for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

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3. Impact Results

Table 18 displays the results of our analysis. The table groups IPFs into the categories listed here based on characteristics provided in the Provider of Services file, the IPF PSF, and cost report data from the Healthcare Cost Report Information System:

- Facility Type.
- Location.
- Teaching Status Adjustment.
- Census Region.
- Size.

The top row of the table shows the overall impact on the 1,519 IPFs included in the analysis for FY 2019 claims or the 1,534 IPFs included in the analysis for FY 2020 claims. In column 2, we present the number of facilities of each type that had information available in the PSF and also had claims in the MedPAR dataset for FY 2019 or FY 2020. The number of providers in each category therefore differs slightly between the two years.

In column 3, we present the effects of the update to the outlier fixed dollar loss threshold amount. Based on the FY 2019 claims, we would estimate that IPF outlier payments as a percentage of total IPF payments are 1.9 percent in FY 2021. Alternatively, based on the FY 2020 claims, we would estimate that IPF outlier payments as a percentage of total IPF payments are 3.1 percent in FY 2021.

Thus, we are finalizing our proposal to adjust the outlier threshold amount in this final rule to set total estimated outlier payments equal to 2.0 percent of total payments in FY 2022. Based on the FY 2019 claims, the estimated change in total IPF payments for FY 2022 would include an approximate 0.1 percent increase in payments because we would expect the outlier portion of total payments to increase from approximately 1.9 percent to 2.0 percent. Alternatively, based on the FY 2020 claims, the estimated change in total IPF payments for FY 2022 would include an approximate 1.1 percent decrease in payments because we would expect the outlier portion of total payments to decrease from approximately 3.1 percent to 2.0 percent.

The overall impact of the estimated increase or decrease to payments due to updating the outlier fixed dollar loss threshold (as shown in column 3 of Table 18), across all hospital groups, is 0.1 percent based on the FY 2019 claims, or –1.1 percent based on the FY 2020 claims. Based on the FY 2019 claims, the largest increase in payments due to this change is estimated to be 0.4 percent for teaching IPFs with more than 30 percent interns and residents to beds. Among teaching IPFs, this same provider facility type would experience the largest estimated decrease in payments if we were to instead increase the outlier fixed dollar loss threshold based on the FY 2020 claims distribution.

In column 4, we present the effects of the budget-neutral update to the IPF wage index, the Labor-Related Share (LRS), and the final updated COLA factors discussed in section III.D.3. This represents the effect of using the concurrent hospital wage data as discussed in section III.D.1.a of this final rule. That is, the impact represented in this column reflects the final updated COLA factors and the update from the FY 2021 IPF wage index to the final FY 2022 IPF wage index, which includes basing the FY 2022 IPF wage index on the FY 2022 pre-floor, pre-reclassified IPPS hospital wage index data and updating the LRS from 77.3 percent in FY 2021 to 77.2 percent in FY 2022. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 4; however, there will be distributional effects among different categories of IPFs. We also note that when comparing the results using

FY 2019 and FY 2020 claims, the distributional effects are very similar. For example, we estimate the largest increase in payments to be 0.6 percent for IPFs in the South Atlantic region, and the largest decrease in payments to be –0.5 percent for IPFs in the East South Central region, based on either the FY 2019 or FY 2020 claims.

Finally, column 5 compares the total final changes reflected in this final rule for FY 2022 to the estimates for FY 2021 (without these changes). The average estimated increase for all IPFs is approximately 2.1 percent based on the FY 2019 claims, or 0.9 percent based on the FY 2020 claims. These estimated net increases include the effects of the 2016-based market basket update of 2.7 percent reduced by the productivity adjustment of 0.7 percentage point, as required by section 1886(s)(2)(A)(i) of the Act. They also include the overall estimated 0.1 percent increase in estimated IPF outlier payments as a percent of total payments from updating the outlier fixed dollar loss threshold amount. In addition, column 5 includes the distributional effects of the final updates to the IPF wage index, the labor-related share, and the final updated COLA factors, whose impacts are displayed in column 4. Based on the FY 2020 claims distribution, the increase to estimated payments due to the market basket update factor are offset in large part for some provider types by the increase to the outlier fixed dollar loss threshold.

In summary, comparing the impact results for the FY 2019 and FY 2020 claims, the largest difference in the results continues to be due to the update to the outlier fixed dollar loss threshold, which is the same result we observed in the FY 2022 IPF PPS proposed rule (86 FR 19524). Estimated outlier payments increased and estimated total PPS payments decreased, when comparing FY 2020 to FY 2019. As a result, we continue to believe that FY 2019 claims, rather than FY 2020 claims, are the best available data for setting the FY 2022 final outlier fixed dollar loss threshold. Furthermore, the distributional effects of the updates presented in column 4 of Table 18 (the budget-neutral update to the IPF wage index, the LRS, and the final updated COLA factors) are very similar when using the FY 2019 or FY 2020 claims data. Therefore, we believe the FY 2019 claims are the best available data for estimating payments in this FY 2022 final rulemaking, and we are finalizing our proposal to use the FY 2019 claims to calculate the outlier fixed dollar loss threshold and wage index budget neutrality factor.

IPF payments are therefore estimated to increase by 2.1 percent in urban areas and 2.2 percent in rural areas based on this finalized policy. Overall, IPFs are estimated to experience a net increase in payments as a result of the updates in this final rule. The largest payment increase is estimated at 2.7 percent for IPFs in the South Atlantic region.

4. Effect on Beneficiaries

Under the FY 2022 IPF PPS, IPFs will continue to receive payment based on the average resources consumed by patients for each day. Our longstanding payment methodology reflects the differences in patient resource use and costs among IPFs, as required under section 124 of the BBRA. We expect that updating IPF PPS rates as finalized in this rule will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in inpatient psychiatric care and the costs of these resources. We continue to expect that paying prospectively for IPF services under the FY 2022 IPF PPS will enhance the efficiency of the Medicare program.

As discussed in sections IV.E.2, IV.E.3, and V.A.2.d of this final rule, we expect that additional program measures will improve follow-up for patients with both mental health and substance use disorders and ensure health-care personnel COVID–19 vaccinations. We also estimate an annualized estimate of $512,065 reduction in information collection burden as a result our measure removals. Therefore, we expect that the final updates to the IPFQR program will improve quality for beneficiaries.

5. Effects of Updates to the IPFQR Program

As discussed in section V. of this final rule and in accordance with section 1886(s)(4)(A)(i) of the Act, we will apply a 2 percentage point reduction to the FY 2022 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for FY 2022, including reporting on the required measures. In section V. of this final rule, we discuss how the 2 percentage point reduction will be applied. For FY 2021, of the 1,634 IPFs eligible for the IPFQR Program, 43 IPFs (2.6 percent) did not receive the full market basket update because of the IPFQR Program; 31 of these IPFs chose not to participate and 12 did not meet the requirements of the program. We anticipate that even fewer IPFs would receive the reduction for FY 2022 as IPFs become more familiar with the requirements. Thus, we estimate that the IPFQR Program will have a negligible impact on overall IPF payments for FY 2022.

Based on the IPFQR Program policies finalized in this final rule, we estimate a total decrease in burden of 287,924 hours across all IPFs, resulting in a total decrease in information collection burden of $512,065 across all IPFs. As discussed in section VI. of this final rule, we will attribute the cost savings associated with the proposals to the year in which these savings begin; for the purposes of all the policies in this final rule, that year is FY 2023. Further information on these estimates can be found in section VI. of this final rule.

We intend to closely monitor the effects of the IPFQR Program on IPFs and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and a technical help desk.

6. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will be directly impacted and will review this final rule, we assume that the total number of unique commenters on the most recent IPF proposed rule will be the number of reviewers of this final rule. For this FY 2022 IPF PPS final rule, the most recent IPF proposed rule was the FY 2022 IPF PPS proposed rule, and we received 898 unique comments on this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the FY 2021 IPF proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons, we thought that the number of commenters would be a fair estimate of the number of reviewers who are directly impacted by this final rule. We solicited comments on this assumption.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule; therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of this final rule.

Using the May, 2020 mean (average) wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this final rule is $114.24 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes119111.htm*). Assuming

an average reading speed of 250 words per minute, we estimate that it would take approximately 128 minutes (2.13 hours) for the staff to review half of this final rule, which is approximately 32,000 words. For each IPF that reviews the final rule, the estimated cost is (2.13 × $114.24) or $243.33. Therefore, we estimate that the total cost of reviewing this final rule is $ 218,510.34 ($243.33 × 898 reviewers).

D. Alternatives Considered

The statute does not specify an update strategy for the IPF PPS and is broadly written to give the Secretary discretion in establishing an update methodology. We continue to believe it is appropriate to routinely update the IPF PPS so that it reflects the best available data about differences in patient resource use and costs among IPFs as required by the statute. Therefore, we are finalizing our proposal to update the IPF PPS using the methodology published in the November 2004 IPF PPS final rule; applying the 2016-based IPF PPS market basket update for FY 2022 of 2.7 percent, reduced by the statutorily required productivity adjustment of 0.7 percentage point along with the wage index budget neutrality adjustment to update the payment rates; and finalizing a FY 2022 IPF wage index which uses the FY 2022 pre-floor, pre-reclassified IPPS hospital wage index as its basis.

As discussed in section VI.C.3 of this final rule, we also considered using FY 2020 claims data to determine the final FY 2022 outlier fixed dollar loss threshold, wage index budget neutrality factor, per diem base rate, and ECT rate. For the reasons discussed in that section, we are finalizing our proposal to use FY 2019 claims data.

E. Accounting Statement

As required by OMB Circular A–4 (available at *www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 19, we have prepared an accounting statement showing the classification of the expenditures associated with the updates to the IPF wage index and payment rates in this final rule. Table 19 provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the changes presented in this final rule and based on the data for 1,519 IPFs with data available in the PSF and with claims in our FY 2019 MedPAR claims dataset. Table 19 also includes our best estimate of the cost savings for the 1,634 IPFs eligible for the IPFQR Program. Lastly, Table 19 also includes our best estimate of the costs of reviewing and understanding this final rule.

TABLE 19: Accounting Statement: Classification of Estimated Costs, Savings, and Transfers

Category	Primary estimate ($million/year)	Low estimate	High estimate	Units		
				Year dollars	Discount rate	Period covered
Regulatory Review Costs	0.2	-	-	2020	-	FY 2022
Annualized Monetized Costs Savings	-0.51	-0.38	-0.64	2019	7%	FY 2023 – FY 2031
	-0.44	-0.33	-0.54	2019	3%	FY 2023 – FY 2031
Annualized Monetized Transfers from Federal Government to IPF Medicare Providers	80	-	-	FY 2022	-	FY 2022

F. Regulatory Flexibility Act

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, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IPFs and most other providers and suppliers are small entities, either by nonprofit status or having revenues of $8 million to $41.5 million or less in any 1 year. Individuals and states are not included in the definition of a small entity.

Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IPFs or the proportion of IPFs' revenue derived from Medicare payments. Therefore, we assume that all IPFs are considered small entities.

The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 18, we estimate that the overall revenue impact of this final rule on all IPFs is to increase estimated Medicare payments by approximately 2.1 percent. As a result, since the estimated impact of this final rule is a net increase in revenue across almost all categories of IPFs, the Secretary has determined that this final rule will have a positive revenue impact on a substantial number of small entities.

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 604 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 fewer than 100 beds. As discussed in section V.C.1 of this final rule, the rates and policies set forth in this final rule will not have an adverse impact on the rural hospitals based on the data of the 239 rural excluded psychiatric units and 60 rural psychiatric hospitals in our database of 1,519 IPFs for which data were available. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandate Reform Act (UMRA)

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. In 2021, that threshold is approximately $158 million. This final rule does not mandate any requirements for state, local, or tribal governments, or for the private sector. This final rule would not impose a mandate that will result in the expenditure by state, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $158 million in any one year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This final rule does not impose substantial direct costs on state or local governments or preempt state law.

I, Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 23, 2021.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.402 is amended by adding definitions for ''Closure of an IPF'', ''Closure of an IPF's residency training program'', and ''Displaced resident'' in alphabetical order to read as follows:

§ 412.402 Definitions.

* * * * *

Closure of an IPF means closure of a hospital as defined in § 413.79(h)(1)(i) by an IPF meeting the requirements of § 412.404(b) for the purposes of accounting for indirect teaching costs.

Closure of an IPF's residency training program means closure of a hospital residency training program as defined in § 413.79(h)(1)(ii) by an IPF meeting the requirements of § 412.404(b) for the purposes of accounting for indirect teaching costs.

* * * * *

Displaced resident means a displaced resident as defined in § 413.79(h)(1)(iii) for the purposes of accounting for indirect teaching costs.

* * * * *

■ 3. Section 412.424 is amended by revising paragraph (d)(1)(iii)(F) to read as follows:

§ 412.424 Methodology for calculating the Federal per diem payment system.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(F) *Closure of an IPF or IPF residency training program*—(*1*) *Closure of an IPF.* For cost reporting periods beginning on or after July 1, 2011, an IPF may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of another IPF's closure if the IPF meets the following criteria:

(*i*) The IPF is training additional displaced residents from an IPF that closed on or after July 1, 2011.

(*ii*) No later than 60 days after the IPF begins to train the displaced residents, the IPF submits a request to its Medicare contractor for a temporary adjustment to its cap, documents that the IPF is eligible for this temporary adjustment by identifying the displaced residents who have come from the closed IPF and have caused the IPF to exceed its cap, and specifies the length of time the adjustment is needed.

(*2*) *Closure of an IPF's residency training program.* If an IPF that closes its residency training program on or after July 1, 2011, agrees to temporarily reduce its FTE cap according to the criteria specified in paragraph (d)(1)(iii)(F)(*2*)(*ii*) of this section, another IPF(s) may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of the closure of the residency training program if the criteria specified in paragraph (d)(1)(iii)(F)(*2*)(*i*) of this section are met.

(*i*) *Receiving IPF(s).* For cost reporting periods beginning on or after July 1, 2011, an IPF may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of the closure of another IPF's residency training program if the IPF is training additional displaced residents from the residency training program of an IPF that closed a program; and if no later than 60 days after the IPF begins to train the displaced residents, the IPF submits to its Medicare Contractor a request for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the displaced residents who have come from another IPF's closed program and have caused the IPF to exceed its cap, specifies the length of time the adjustment is needed, and submits to its Medicare contractor a copy of the FTE reduction statement by the hospital that closed its program, as specified in paragraph (d)(1)(iii)(F)(*2*)(*ii*) of this section.

(*ii*) *IPF that closed its program.* An IPF that agrees to train displaced residents who have been displaced by the closure of another IPF's program may receive a temporary FTE cap adjustment only if the hospital with the closed program temporarily reduces its FTE cap based on the FTE of displaced residents in each program year training in the program at the time of the program's closure. This yearly reduction in the FTE cap will be determined based on the number of those displaced residents who would have been training in the program during that year had the program not closed. No later than 60 days after the displaced residents who were in the closed program begin training at another hospital, the hospital with the closed program must submit to its Medicare contractor a statement signed and dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the IPF training the displaced residents to obtain a temporary adjustment to its cap; identifies the displaced residents who were in training at the time of the program's closure; identifies the IPFs to which the displaced residents are transferring once the program closes; and specifies the reduction for the applicable program years.

* * * * *

■ 4. Section 412.434 is amended by revising paragraph (b)(3) to read as follows:

§ 412.434 Reconsideration and appeals procedures of Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program decisions

* * * * *

(b) * * *

(3) Contact information for the inpatient psychiatric facility's chief executive officer and QualityNet security official, including each individual's name, email address, telephone number, and physical mailing address;

* * * * *

Dated: July 27, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–16336 Filed 7–29–21; 4:15 pm]

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